US3952094 (Prod: Synexus - Optimal Research - Rockville)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:28:25

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**US3952094**
**Form: Participant Creation**
**Data signed:** (b) (4) **08 Apr 2021 19:48:07**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Participant ID | US3952094 |

mRNA-1273-P301 Completion Guidelines



FDA-CBER-2022-1614-3795907

**US3952094**
**Folder: Screening**
**Form: Visit Date**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was this visit performed? | Yes ☑<br>No ☐ |
| Visit date (dd MMM yyyy) | 15 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home ☐<br>Clinic ☑ |
| Folder OID | SCRN |



FDA-CBER-2022-1614-3795908

**US3952094**
**Folder: Screening**
**Form: Demographics**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Date of Birth (MMM yyyy) | (b) (6) 1963 |
| Age | 57 |
| Age Units | YEARS |
| Age (Derived) | 57 |
| Sex | Female ☐ |
| | Male ■ |
| Ethnicity | Hispanic or Latino ■ |
| | Not Hispanic or Latino ☐ |
| | Not Reported ☐ |
| | Unknown ☐ |
| 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 |



FDA-CBER-2022-1614-3795909

**US3952094**
**Folder: Screening**
**Form: Enrollment**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Date of Informed Consent *(dd MMM yyyy)* | 15 SEP 2020 |
| Month and Year of Informed Consent (derived) | SEP 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 ☐<br>Amendment 2 ☐<br>Amendment 3 ■<br>Amendment 4 ☐<br>Amendment 5 ☐ |
| Was participant enrolled in the study? | Yes ■<br>No ☐ |
| If No, indicate reason for screen fail | Withdrew Consent ☐<br>Inclusion/Exclusion ☐<br>Cohort Full ☐<br>Other ☐ |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes ☐<br>No ■ |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |



FDA-CBER-2022-1614-3795910

**US3952094**
**Folder: Screening**
**Form: Inclusion/Exclusion Criteria Summary**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Did the participant meet all eligibility criteria? | Yes ■<br>No ☐ |



FDA-CBER-2022-1614-3795911

**US3952094**
**Folder: Screening**
**Form: Medical History Summary**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Were any significant conditions reported? | Yes ■<br>No ☐ |



FDA-CBER-2022-1614-3795912

**US3952094**
**Folder: Screening**
**Form: Medical History (1)**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Condition | HYPERTENSION |
| Start date (dd MMM yyyy) | UN UNK 2010 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ☒<br>No ☐ |
| 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) | |



FDA-CBER-2022-1614-3795913

**US3952094**
**Folder: Screening**
**Form: Medical History (2)**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Condition | HIGH CHOLESTEROL |
| Start date (dd MMM yyyy) | UN UNK 2010 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ☒<br>No ☐ |
| 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) | |



FDA-CBER-2022-1614-3795914

**US3952094**
**Folder: Screening**
**Form: Medical History (3)**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Condition | DIABETES |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ☒<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |



FDA-CBER-2022-1614-3795915

**US3952094**
**Folder: Screening**
**Form: Medical History (4)**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Condition | NECK HERNIA |
| Start date (dd MMM yyyy) | UN UNK 2008 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ☒<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2008 |
| Start Year (derived) | 2008 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |



FDA-CBER-2022-1614-3795916

**US3952094**
**Folder: Screening**
**Form: Medical History (5)**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Condition | LEFT KNEE PAIN |
| Start date (dd MMM yyyy) | 27 FEB 2020 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes ■<br>No ☐ |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | FEB 2020 |
| Start Year (derived) | 2020 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |



FDA-CBER-2022-1614-3795917

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Were vital signs assessed? | Yes ☒<br>No ☐ |
| Date of assessment *(dd MMM yyyy)* | 15 SEP 2020 |
| Time of assessment *(00:00-23:59)* | 12:03 (24 HR) |
| Vital Signs Date and Time (derived) | 15 SEP 2020 12:03 |
| Height *(xxx.x)* | 60.0 in |
| Weight *(xxx.x)* | 140.0 lb |
| BMI *(xxx.x)* | 27.39904 $kg/m^2$ |
| BMI units | KG/M2 |
| Temperature *(xxx.x)* | ND - Not Done |
| Route of measurement | Oral ☐<br>Axillary ☐<br>Other ☐ |
| 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) | |

**US3952094**
**Folder: Screening**
**Form: Physical Examination**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was the physical examination performed? | Yes ☑<br>No ☐ |
| Date of examination *(dd MMM yyyy)* | 15 SEP 2020 |

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



FDA-CBER-2022-1614-3795919

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| **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** | WALKS 5 MILES DAILY (MONDAY THROUGH FRIDAY). GROCERIES ONCE WEEKLY. |

| **Location and Living Circumstances Risk (check all that apply)** | |
|---|---|
| **No Risk Identified** | False |
| **Resides in Nursing Home or Assisted Living Facility** | False |

| | |
|---|---|
| **Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) | False |
| **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** | True |
| **Specify** | RENTS A ROOM WITH ONE ROOMMATE |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Visit Date**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was this visit performed? | Yes ☑<br>No ☐ |
| Visit date (dd MMM yyyy) | 15 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home ☐<br>Clinic ☑ |
| Folder OID | VISIT1 |



FDA-CBER-2022-1614-3795922

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| What was the date of randomization? *(dd MMM yyyy)* | 15 SEP 2020 |
| What was the participant's randomization number? | 145978 |
| In what Cohort was the participant enrolled? | >=18 and <65 years and not at risk ☐<br>>=18 and <65 years and at risk ■<br>>=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 ☐<br>No ■ |
| Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) | Yes ☐<br>No ■ |
| Severe obesity (body mass index > or = 40kg/m2 | Yes ☐<br>No ■ |
| Diabetes (Type I, Type 2, or gestational) | Yes ■<br>No ☐ |
| Liver Disease | Yes ☐<br>No ■ |
| Human Immunodeficiency Virus (HIV) infection | Yes ☐<br>No ■ |



FDA-CBER-2022-1614-3795923

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

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



FDA-CBER-2022-1614-3795924

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose ■<br>Post-Dose ☐ |
| Were vital signs assessed? | Yes ■<br>No ☐ |
| Date of assessment *(dd MMM yyyy)* | 15 SEP 2020 |
| Time of assessment *(00:00-23:59)* | 12:03 (24 HR) |
| Vital Signs Date and Time (derived) | 15 SEP 2020 12:03 |
| Temperature *(xxx.x)* | 36.8 C |
| Route of measurement | Oral ■<br>Axillary ☐<br>Other ☐ |
| If Other, specify | |
| Pulse *(xxx)* | 68 beats/min |
| Pulse units | BPM |
| Respiratory Rate *(xxx)* | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure *(xxx)* | 144 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure *(xxx)* | 83 mmHg |
| Diastolic Blood Pressure units | MMHG |



FDA-CBER-2022-1614-3795925

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose ☐<br>Post-Dose ■ |
| Were vital signs assessed? | Yes ■<br>No ☐ |
| Date of assessment *(dd MMM yyyy)* | 15 SEP 2020 |
| Time of assessment *(00:00-23:59)* | 15:20 (24 HR) |
| Vital Signs Date and Time (derived) | 15 SEP 2020 15:20 |
| Temperature *(xxx.x)* | 36.5 C |
| Route of measurement | Oral ■<br>Axillary ☐<br>Other ☐ |
| If Other, specify | |
| Pulse *(xxx)* | 57 beats/min |
| Pulse units | BPM |
| Respiratory Rate *(xxx)* | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure *(xxx)* | 145 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure *(xxx)* | 72 mmHg |
| Diastolic Blood Pressure units | MMHG |



FDA-CBER-2022-1614-3795926

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Physical Examination**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was the physical examination performed? | Yes ☐<br>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.***



FDA-CBER-2022-1614-3795927

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was study treatment given? | Yes ■<br>No ☐ |
| If No, reason not given | Participant declined due to Adverse Event ☐<br>Physician withheld dose due to Adverse Event ☐<br>Death ☐<br>Lost To Follow-Up ☐<br>Physician Decision ☐<br>Pregnancy ☐<br>Protocol Deviation ☐<br>Study Terminated by Sponsor ☐<br>Withdrawal of Consent by Participant ☐<br>Confirmed COVID-19 ☐<br>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)* | 15 SEP 2020 |
| What was the treatment time? *(00:00-23:59)* | 13:52 (24 HR) |
| Treatment Date and Time (derived) | 15 SEP 2020 13:52 |
| Which arm was used to give treatment? | Left Arm ■<br>Right Arm ☐ |
| What was the frequency of the study treatment dosing? | ONCE |
| What was the route of administration for the study treatment? | INTRAMUSCULAR |



FDA-CBER-2022-1614-3795928

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Immunogenicity Assessment**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was the sample collected? | Yes ☑ No ☐ |
| Collection date *(dd MMM yyyy)* | 15 SEP 2020 |
| Collection time *(00:00-23:59)* | 12:41 (24 HR) |
| Collection date and time (derived) | 15 SEP 2020 12:41 |



FDA-CBER-2022-1614-3795929

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| Collection date *(dd MMM yyyy)* | | | 15 SEP 2020 |
|---|---|---|---|
| Lab Test | Was the sample collected? | Collection time *(00:00 - 23:59)* | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 12:44 | 15 SEP 2020 12:44 |
| Nasopharyngeal Swab 2 | No | | |



FDA-CBER-2022-1614-3795930

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Continuing**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-3795931

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| **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 ■<br>No ☐ |
| Please record your **TEMPERATURE in °F** | 97.1 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ☐<br>No ■ |
| Please confirm reason for pain or fever medication (may select more than one): | |
| PC Time Stamp | 15 SEP 2020 15:26 |
| PC Open Date & Time | 15 SEP 2020 14:12 |
| PC Close Date & Time | 15 SEP 2020 16:42 |



FDA-CBER-2022-1614-3795932

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| **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 ■<br>No ☐ |
| Please record your **TEMPERATURE in °F** | 97.3 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ☐<br>No ■ |
| Please confirm reason for pain or fever medication (may select more than one): | |
| PC Time Stamp | 15 SEP 2020 22:03 |
| PC Open Date & Time | 15 SEP 2020 17:37 |
| PC Close Date & Time | 16 SEP 2020 11:59 |



FDA-CBER-2022-1614-3795933

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**

| **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 ■<br>No ☐ |
| Please record your **TEMPERATURE in °F** | 97.3 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ☐<br>No ■ |
| Please confirm reason for pain or fever medication (may select more than one): | |
| PC Time Stamp | 16 SEP 2020 21:46 |
| PC Open Date & Time | 16 SEP 2020 12:00 |
| PC Close Date & Time | 17 SEP 2020 11:59 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**

| **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** | 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 | 18 SEP 2020 11:03 |
| PC Open Date & Time | 17 SEP 2020 12:00 |
| PC Close Date & Time | 18 SEP 2020 11:59 |



FDA-CBER-2022-1614-3795935

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**

| **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 ■<br>No ☐ |
| Please record your **TEMPERATURE in °F** | 98.1 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ☐<br>No ■ |
| Please confirm reason for pain or fever medication (may select more than one): | |
| PC Time Stamp | 18 SEP 2020 21:28 |
| PC Open Date & Time | 18 SEP 2020 12:00 |
| PC Close Date & Time | 19 SEP 2020 11:59 |



FDA-CBER-2022-1614-3795936

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**

| **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 ■<br>No ☐ |
| Please record your **TEMPERATURE in °F** | 95.7 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ☐<br>No ■ |
| Please confirm reason for pain or fever medication (may select more than one): | |
| PC Time Stamp | 19 SEP 2020 23:16 |
| PC Open Date & Time | 19 SEP 2020 12:00 |
| PC Close Date & Time | 20 SEP 2020 11:59 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**

| **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** | 95.7 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ○ |
| | No ● |
| Please confirm reason for pain or fever medication (may select more than one): | |
| PC Time Stamp | 20 SEP 2020 22:04 |
| PC Open Date & Time | 20 SEP 2020 12:00 |
| PC Close Date & Time | 21 SEP 2020 11:59 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**

| **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 ■<br>No ☐ |
| Please record your **TEMPERATURE in °F** | 96.8 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ☐<br>No ■ |
| Please confirm reason for pain or fever medication (may select more than one): | |
| PC Time Stamp | 21 SEP 2020 22:00 |
| PC Open Date & Time | 21 SEP 2020 12:00 |
| PC Close Date & Time | 22 SEP 2020 11:59 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| **TIMEPOINT** | DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC) |
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ●<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ● |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ● |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ●<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 15 SEP 2020 15:27 |
| PC Open Date & Time | 15 SEP 2020 14:12 |
| PC Close Date & Time | 15 SEP 2020 16:42 |



FDA-CBER-2022-1614-3795940

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 1, AFTER VACCINATION (AT HOME) |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ☐<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ☐ |
| Please record - **REDNESS AT INJECTION SITE (in mm)**<br><br>Measure the largest size across any injection site redness with the ruler provided. | |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ☐ |
| Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**<br><br>Measure the largest size across any injection site swelling/hardness with the ruler provided. | |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ☐<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | |
| PC Open Date & Time | 15 SEP 2020 17:37 |
| PC Close Date & Time | 16 SEP 2020 11:59 |



FDA-CBER-2022-1614-3795941

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 2 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 16 SEP 2020 21:49 |
| PC Open Date & Time | 16 SEP 2020 12:00 |
| PC Close Date & Time | 17 SEP 2020 11:59 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 3 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 18 SEP 2020 11:05 |
| PC Open Date & Time | 17 SEP 2020 12:00 |
| PC Close Date & Time | 18 SEP 2020 11:59 |



FDA-CBER-2022-1614-3795943

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 4 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 18 SEP 2020 21:29 |
| PC Open Date & Time | 18 SEP 2020 12:00 |
| PC Close Date & Time | 19 SEP 2020 11:59 |



FDA-CBER-2022-1614-3795944

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 5 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 19 SEP 2020 23:17 |
| PC Open Date & Time | 19 SEP 2020 12:00 |
| PC Close Date & Time | 20 SEP 2020 11:59 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 6 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 20 SEP 2020 22:06 |
| PC Open Date & Time | 20 SEP 2020 12:00 |
| PC Close Date & Time | 21 SEP 2020 11:59 |



FDA-CBER-2022-1614-3795946

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 7 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 21 SEP 2020 22:00 |
| PC Open Date & Time | 21 SEP 2020 12:00 |
| PC Close Date & Time | 22 SEP 2020 11:59 |

| | |
|---|---|
| **TIMEPOINT** | DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC) |
| **HEADACHE** | None ■<br>No interference with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| **FATIGUE** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **MUSCLE ACHES ALL OVER BODY** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **JOINT ACHES IN SEVERAL JOINTS** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **NAUSEA/VOMITING** | None ■<br>No interference with activity or 1-2 episodes/24 hours ☐<br>Some interference with activity or >2 episodes/24 hours ☐<br>Prevents daily activity, requires outpatient IV hydration ☐ |
| **CHILLS** | None ■<br>No interference with activity ☐<br>Some interference with activity not requiring medical attention ☐<br>Prevents daily activity and requires medical attention ☐ |



FDA-CBER-2022-1614-3795948

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ☑<br>Yes ☐ |
| PC Time stamp | 15 SEP 2020 15:27 |
| PC Open Date & Time | 15 SEP 2020 14:12 |
| PC Close Date & Time | 15 SEP 2020 16:42 |

| **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 ☐ |



FDA-CBER-2022-1614-3795950

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ☐ Yes ☐ |
| PC Time stamp | |
| PC Open Date & Time | 15 SEP 2020 17:37 |
| PC Close Date & Time | 16 SEP 2020 11:59 |



FDA-CBER-2022-1614-3795951

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**

| **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 ■ |



FDA-CBER-2022-1614-3795952

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**

| | Yes ☐ |
|---|---|
| PC Time stamp | 16 SEP 2020 21:47 |
| PC Open Date & Time | 16 SEP 2020 12:00 |
| PC Close Date & Time | 17 SEP 2020 11:59 |



FDA-CBER-2022-1614-3795953

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**

| **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 ■ |



FDA-CBER-2022-1614-3795954

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**

| | Yes ☐ |
|---|---|
| PC Time stamp | 18 SEP 2020 11:04 |
| PC Open Date & Time | 17 SEP 2020 12:00 |
| PC Close Date & Time | 18 SEP 2020 11:59 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**

| **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 ■ |



FDA-CBER-2022-1614-3795956

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**

| | Yes ☐ |
|---|---|
| PC Time stamp | 18 SEP 2020 21:29 |
| PC Open Date & Time | 18 SEP 2020 12:00 |
| PC Close Date & Time | 19 SEP 2020 11:59 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**

| **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 ■ |



FDA-CBER-2022-1614-3795958

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**

| | Yes ☐ |
|---|---|
| PC Time stamp | 19 SEP 2020 23:17 |
| PC Open Date & Time | 19 SEP 2020 12:00 |
| PC Close Date & Time | 20 SEP 2020 11:59 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| **TIMEPOINT** | DAY 6 |
| **HEADACHE** | None ■<br>No interference with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| **FATIGUE** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **MUSCLE ACHES ALL OVER BODY** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **JOINT ACHES IN SEVERAL JOINTS** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **NAUSEA/VOMITING** | None ■<br>No interference with activity or 1-2 episodes/24 hours ☐<br>Some interference with activity or >2 episodes/24 hours ☐<br>Prevents daily activity, requires outpatient IV hydration ☐ |
| **CHILLS** | None ■<br>No interference with activity ☐<br>Some interference with activity not requiring medical attention ☐<br>Prevents daily activity and requires medical attention ☐ |
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ■ |



FDA-CBER-2022-1614-3795960

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**

| | Yes ☐ |
|---|---|
| PC Time stamp | 20 SEP 2020 22:05 |
| PC Open Date & Time | 20 SEP 2020 12:00 |
| PC Close Date & Time | 21 SEP 2020 11:59 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**

| **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 ■ |



FDA-CBER-2022-1614-3795962

| | |
|---|---|
| | Yes ☐ |
| PC Time stamp | 21 SEP 2020 22:01 |
| PC Open Date & Time | 21 SEP 2020 12:00 |
| PC Close Date & Time | 22 SEP 2020 11:59 |

**US3952094**
**Folder: Safety Call Day 8 (1)**
**Form: Safety Call**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was Contact Attempted? | Yes ■<br>No ☐ |
| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 23 SEP 2020 |
| Please select one status for the follow-up contact | Contact Made ■<br>Contact Not Made ☐ |
| Comments | |
| *If Contact Not Made, please provide Comments* | |



FDA-CBER-2022-1614-3795964

**US3952094**
**Folder: Safety Call Day 8 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-3795965

**US3952094**
**Folder: Safety Call Day 15 (1)**
**Form: Safety Call**
**Data signed:** (b) (4) **19 Feb 2021 21:16:01**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was Contact Attempted? | Yes ■<br>No ☐ |
| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 29 SEP 2020 |
| Please select one status for the follow-up contact | Contact Made ■<br>Contact Not Made ☐ |
| Comments<br><br>*If Contact Not Made, please provide Comments* | |



FDA-CBER-2022-1614-3795966

**US3952094**
**Folder: Safety Call Day 15 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **19 Feb 2021 21:16:01**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-3795967

**US3952094**
**Folder: Safety Call Day 22 (1)**
**Form: Safety Call**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was Contact Attempted? | Yes ■<br>No ☐ |
| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 06 OCT 2020 |
| Please select one status for the follow-up contact | Contact Made ■<br>Contact Not Made ☐ |
| Comments<br><br>*If Contact Not Made, please provide Comments* | |



FDA-CBER-2022-1614-3795968

**US3952094**
**Folder: Safety Call Day 22 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **19 Feb 2021 21:16:01**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-3795969

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Visit Date**
**Data signed:** (b) (4) **19 Feb 2021 21:16:41**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was this visit performed? | Yes ☑<br>No ☐ |
| Visit date (dd MMM yyyy) | 14 OCT 2020 |
| Was visit performed at the participant's home or at the clinic? | Home ☐<br>Clinic ☑ |
| Folder OID | VISIT2 |



FDA-CBER-2022-1614-3795970

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Data signed:** (b) (4) **19 Feb 2021 21:16:41**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Timepoint | Pre-Dose ■<br>Post-Dose ☐ |
| Were vital signs assessed? | Yes ■<br>No ☐ |
| Date of assessment *(dd MMM yyyy)* | 14 OCT 2020 |
| Time of assessment *(00:00-23:59)* | 12:00 (24 HR) |
| Vital Signs Date and Time (derived) | 14 OCT 2020 12:00 |
| Temperature *(xxx.x)* | 37.1 C |
| Route of measurement | Oral ■<br>Axillary ☐<br>Other ☐ |
| If Other, specify | |
| Pulse *(xxx)* | 71 beats/min |
| Pulse units | BPM |
| Respiratory Rate *(xxx)* | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure *(xxx)* | 117 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure *(xxx)* | 61 mmHg |
| Diastolic Blood Pressure units | MMHG |



FDA-CBER-2022-1614-3795971

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Data signed:** (b) (4) **19 Feb 2021 21:16:41**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Timepoint | Pre-Dose ☐<br>Post-Dose ■ |
| Were vital signs assessed? | Yes ■<br>No ☐ |
| Date of assessment *(dd MMM yyyy)* | 14 OCT 2020 |
| Time of assessment *(00:00-23:59)* | 14:08 (24 HR) |
| Vital Signs Date and Time (derived) | 14 OCT 2020 14:08 |
| Temperature *(xxx.x)* | 36.7 C |
| Route of measurement | Oral ■<br>Axillary ☐<br>Other ☐ |
| If Other, specify | |
| Pulse *(xxx)* | 69 beats/min |
| Pulse units | BPM |
| Respiratory Rate *(xxx)* | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure *(xxx)* | 126 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure *(xxx)* | 60 mmHg |
| Diastolic Blood Pressure units | MMHG |



FDA-CBER-2022-1614-3795972

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Physical Examination**
**Data signed:** (b) (4) **19 Feb 2021 21:16:41**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was the physical examination performed? | Yes ☑<br>No ☐ |
| Date of examination *(dd MMM yyyy)* | 14 OCT 2020 |

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



FDA-CBER-2022-1614-3795973

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was study treatment given? | Yes ■<br>No ☐ |
| If No, reason not given | Participant declined due to Adverse Event ☐<br>Physician withheld dose due to Adverse Event ☐<br>Death ☐<br>Lost To Follow-Up ☐<br>Physician Decision ☐<br>Pregnancy ☐<br>Protocol Deviation ☐<br>Study Terminated by Sponsor ☐<br>Withdrawal of Consent by Participant ☐<br>Confirmed COVID-19 ☐<br>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)* | 14 OCT 2020 |
| What was the treatment time? *(00:00-23:59)* | 13:03 (24 HR) |
| Treatment Date and Time (derived) | 14 OCT 2020 13:03 |
| Which arm was used to give treatment? | Left Arm ■<br>Right Arm ☐ |
| What was the frequency of the study treatment dosing? | ONCE |
| What was the route of administration for the study treatment? | INTRAMUSCULAR |



FDA-CBER-2022-1614-3795974

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Immunogenicity Assessment**
**Data signed:** (b) (4) **19 Feb 2021 21:16:41**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was the sample collected? | Yes ☑ No ☐ |
| Collection date *(dd MMM yyyy)* | 14 OCT 2020 |
| Collection time *(00:00-23:59)* | 12:29 (24 HR) |
| Collection date and time (derived) | 14 OCT 2020 12:29 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| Collection date *(dd MMM yyyy)* | | | 14 OCT 2020 |
|---|---|---|---|
| Lab Test | Was the sample collected? | Collection time *(00:00 - 23:59)* | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 12:31 | 14 OCT 2020 12:31 |
| Nasopharyngeal Swab 2 | No | | |



FDA-CBER-2022-1614-3795976

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ☑<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-3795977

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| **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 ■<br>No ☐ |
| Please record your **TEMPERATURE in °F** | 98.0 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ☐<br>No ■ |
| Please confirm reason for pain or fever medication (may select more than one): | |
| PC Time Stamp | 14 OCT 2020 14:06 |
| PC Open Date & Time | 14 OCT 2020 13:23 |
| PC Close Date & Time | 14 OCT 2020 15:53 |



FDA-CBER-2022-1614-3795978

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**

| **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 ■<br>No ☐ |
| Please record your **TEMPERATURE in °F** | 98.3 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ☐<br>No ■ |
| Please confirm reason for pain or fever medication (may select more than one): | |
| PC Time Stamp | 14 OCT 2020 22:00 |
| PC Open Date & Time | 14 OCT 2020 16:48 |
| PC Close Date & Time | 15 OCT 2020 11:59 |



FDA-CBER-2022-1614-3795979

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**

| **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** | 97.3 °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 | 15 OCT 2020 22:29 |
| PC Open Date & Time | 15 OCT 2020 12:00 |
| PC Close Date & Time | 16 OCT 2020 11:59 |



FDA-CBER-2022-1614-3795980

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 3 |
|---|---|

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

| | |
|---|---|
| Was **TEMPERATURE** taken? | Yes ● |
| | No ○ |
| Please record your **TEMPERATURE in °F** | 98.0 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ○ |
| | No ● |
| Please confirm reason for pain or fever medication (may select more than one): | |
| PC Time Stamp | 16 OCT 2020 23:01 |
| PC Open Date & Time | 16 OCT 2020 12:00 |
| PC Close Date & Time | 17 OCT 2020 11:59 |



FDA-CBER-2022-1614-3795981

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 4 |
|---|---|

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

| | |
|---|---|
| Was **TEMPERATURE** taken? | Yes ● |
| | No ○ |
| Please record your **TEMPERATURE in °F** | 98.3 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ○ |
| | No ● |
| Please confirm reason for pain or fever medication (may select more than one): | |
| PC Time Stamp | 18 OCT 2020 04:07 |
| PC Open Date & Time | 17 OCT 2020 12:00 |
| PC Close Date & Time | 18 OCT 2020 11:59 |



FDA-CBER-2022-1614-3795982

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 5 |
|---|---|

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

| | |
|---|---|
| Was **TEMPERATURE** taken? | Yes ● |
| | No ○ |
| Please record your **TEMPERATURE in °F** | 97.8 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ○ |
| | No ● |
| Please confirm reason for pain or fever medication (may select more than one): | |
| PC Time Stamp | 18 OCT 2020 22:25 |
| PC Open Date & Time | 18 OCT 2020 12:00 |
| PC Close Date & Time | 19 OCT 2020 11:59 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**

| **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** | 96.5 °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 | 19 OCT 2020 21:15 |
| PC Open Date & Time | 19 OCT 2020 12:00 |
| PC Close Date & Time | 20 OCT 2020 11:59 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 7 |
|---|---|

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

| | |
|---|---|
| Was **TEMPERATURE** taken? | Yes ● |
| | No ○ |
| Please record your **TEMPERATURE in °F** | 98.2 °F |
| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ○ |
| | No ● |
| Please confirm reason for pain or fever medication (may select more than one): | |
| PC Time Stamp | 21 OCT 2020 10:23 |
| PC Open Date & Time | 20 OCT 2020 12:00 |
| PC Close Date & Time | 21 OCT 2020 11:59 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| **TIMEPOINT** | DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC) |
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 14 OCT 2020 14:06 |
| PC Open Date & Time | 14 OCT 2020 13:23 |
| PC Close Date & Time | 14 OCT 2020 15:53 |



FDA-CBER-2022-1614-3795986

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 1, AFTER VACCINATION (AT HOME) |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 14 OCT 2020 22:00 |
| PC Open Date & Time | 14 OCT 2020 16:48 |
| PC Close Date & Time | 15 OCT 2020 11:59 |



FDA-CBER-2022-1614-3795987

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 2 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 15 OCT 2020 22:30 |
| PC Open Date & Time | 15 OCT 2020 12:00 |
| PC Close Date & Time | 16 OCT 2020 11:59 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 3 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 16 OCT 2020 23:02 |
| PC Open Date & Time | 16 OCT 2020 12:00 |
| PC Close Date & Time | 17 OCT 2020 11:59 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 4 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 18 OCT 2020 04:08 |
| PC Open Date & Time | 17 OCT 2020 12:00 |
| PC Close Date & Time | 18 OCT 2020 11:59 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 5 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 18 OCT 2020 22:25 |
| PC Open Date & Time | 18 OCT 2020 12:00 |
| PC Close Date & Time | 19 OCT 2020 11:59 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 6 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ■ |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ■<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 19 OCT 2020 21:16 |
| PC Open Date & Time | 19 OCT 2020 12:00 |
| PC Close Date & Time | 20 OCT 2020 11:59 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 7 |
|---|---|
| Please record - **PAIN AT INJECTION SITE.**<br>Please select one response below | None ●<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| Is there any **REDNESS AT INJECTION SITE**? | Yes ☐<br>No ● |
| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ☐<br>No ● |
| Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**<br>Please select one response below | None ●<br>Does not interfere with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| PC Time Stamp | 21 OCT 2020 10:23 |
| PC Open Date & Time | 20 OCT 2020 12:00 |
| PC Close Date & Time | 21 OCT 2020 11:59 |

| | |
|---|---|
| **TIMEPOINT** | DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC) |
| **HEADACHE** | None ■<br>No interference with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| **FATIGUE** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **MUSCLE ACHES ALL OVER BODY** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **JOINT ACHES IN SEVERAL JOINTS** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **NAUSEA/VOMITING** | None ■<br>No interference with activity or 1-2 episodes/24 hours ☐<br>Some interference with activity or >2 episodes/24 hours ☐<br>Prevents daily activity, requires outpatient IV hydration ☐ |
| **CHILLS** | None ■<br>No interference with activity ☐<br>Some interference with activity not requiring medical attention ☐<br>Prevents daily activity and requires medical attention ☐ |



FDA-CBER-2022-1614-3795994

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ■<br>Yes ☐ |
| PC Time stamp | 14 OCT 2020 14:07 |
| PC Open Date & Time | 14 OCT 2020 13:23 |
| PC Close Date & Time | 14 OCT 2020 15:53 |



FDA-CBER-2022-1614-3795995

| **TIMEPOINT** | DAY 1, AFTER VACCINATION (AT HOME) |
|---|---|
| **HEADACHE** | None ■<br>No interference with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| **FATIGUE** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **MUSCLE ACHES ALL OVER BODY** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **JOINT ACHES IN SEVERAL JOINTS** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **NAUSEA/VOMITING** | None ■<br>No interference with activity or 1-2 episodes/24 hours ☐<br>Some interference with activity or >2 episodes/24 hours ☐<br>Prevents daily activity, requires outpatient IV hydration ☐ |
| **CHILLS** | None ■<br>No interference with activity ☐<br>Some interference with activity not requiring medical attention ☐<br>Prevents daily activity and requires medical attention ☐ |



FDA-CBER-2022-1614-3795996

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ■<br>Yes ☐ |
| PC Time stamp | 14 OCT 2020 22:01 |
| PC Open Date & Time | 14 OCT 2020 16:48 |
| PC Close Date & Time | 15 OCT 2020 11:59 |



FDA-CBER-2022-1614-3795997

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**

| **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 ■ |



FDA-CBER-2022-1614-3795998

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**

| | Yes ☐ |
|---|---|
| PC Time stamp | 15 OCT 2020 22:30 |
| PC Open Date & Time | 15 OCT 2020 12:00 |
| PC Close Date & Time | 16 OCT 2020 11:59 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| **TIMEPOINT** | DAY 3 |
| **HEADACHE** | None ■<br>No interference with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| **FATIGUE** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **MUSCLE ACHES ALL OVER BODY** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **JOINT ACHES IN SEVERAL JOINTS** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **NAUSEA/VOMITING** | None ■<br>No interference with activity or 1-2 episodes/24 hours ☐<br>Some interference with activity or >2 episodes/24 hours ☐<br>Prevents daily activity, requires outpatient IV hydration ☐ |
| **CHILLS** | None ■<br>No interference with activity ☐<br>Some interference with activity not requiring medical attention ☐<br>Prevents daily activity and requires medical attention ☐ |
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ■ |



FDA-CBER-2022-1614-3796000

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**

| | Yes ☐ |
|---|---|
| PC Time stamp | 16 OCT 2020 23:03 |
| PC Open Date & Time | 16 OCT 2020 12:00 |
| PC Close Date & Time | 17 OCT 2020 11:59 |



FDA-CBER-2022-1614-3796001

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| **TIMEPOINT** | DAY 4 |
| **HEADACHE** | None ■<br>No interference with activity ☐<br>Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐<br>Any use of prescription pain reliever or prevents daily activity ☐ |
| **FATIGUE** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **MUSCLE ACHES ALL OVER BODY** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **JOINT ACHES IN SEVERAL JOINTS** | None ■<br>No interference with activity ☐<br>Some interference with activity ☐<br>Significant; prevents daily activity ☐ |
| **NAUSEA/VOMITING** | None ■<br>No interference with activity or 1-2 episodes/24 hours ☐<br>Some interference with activity or >2 episodes/24 hours ☐<br>Prevents daily activity, requires outpatient IV hydration ☐ |
| **CHILLS** | None ■<br>No interference with activity ☐<br>Some interference with activity not requiring medical attention ☐<br>Prevents daily activity and requires medical attention ☐ |
| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ■ |



FDA-CBER-2022-1614-3796002

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**

| | Yes ☐ |
|---|---|
| PC Time stamp | 18 OCT 2020 04:08 |
| PC Open Date & Time | 17 OCT 2020 12:00 |
| PC Close Date & Time | 18 OCT 2020 11:59 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**

| **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 ■ |



FDA-CBER-2022-1614-3796004

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**

| | Yes ☐ |
|---|---|
| PC Time stamp | 18 OCT 2020 22:26 |
| PC Open Date & Time | 18 OCT 2020 12:00 |
| PC Close Date & Time | 19 OCT 2020 11:59 |



FDA-CBER-2022-1614-3796005

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| **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 ■ |



FDA-CBER-2022-1614-3796006

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**

| | Yes ☐ |
|---|---|
| PC Time stamp | 19 OCT 2020 21:16 |
| PC Open Date & Time | 19 OCT 2020 12:00 |
| PC Close Date & Time | 20 OCT 2020 11:59 |

| **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 ■ |



FDA-CBER-2022-1614-3796008

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**

| | Yes ☐ |
|---|---|
| PC Time stamp | 21 OCT 2020 10:23 |
| PC Open Date & Time | 20 OCT 2020 12:00 |
| PC Close Date & Time | 21 OCT 2020 11:59 |

**US3952094**
**Folder: Safety Call Day 36 (1)**
**Form: Safety Call**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was Contact Attempted? | Yes ☐<br>No ■ |
| Date of Contact or Contact Attempt *(dd MMM yyyy)* | |
| Please select one status for the follow-up contact | Contact Made ☐<br>Contact Not Made ☐ |
| Comments<br><br>*If Contact Not Made, please provide Comments* | |



FDA-CBER-2022-1614-3796010

**US3952094**
**Folder: Safety Call Day 36 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-3796011

**US3952094**
**Folder: Safety Call Day 43 (1)**
**Form: Safety Call**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was Contact Attempted? | Yes ■<br>No ☐ |
| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 28 OCT 2020 |
| Please select one status for the follow-up contact | Contact Made ■<br>Contact Not Made ☐ |
| Comments | |
| *If Contact Not Made, please provide Comments* | |



FDA-CBER-2022-1614-3796012

**US3952094**
**Folder: Safety Call Day 43 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-3796013

**US3952094**
**Folder: Safety Call Day 50 (1)**
**Form: Safety Call**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was Contact Attempted? | Yes ■<br>No ☐ |
| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 04 NOV 2020 |
| Please select one status for the follow-up contact | Contact Made ■<br>Contact Not Made ☐ |
| Comments | |
| *If Contact Not Made, please provide Comments* | |

**US3952094**
**Folder: Safety Call Day 50 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **19 Feb 2021 21:16:40**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-3796015

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Visit Date**
**Data signed:** (b) (4) **19 Feb 2021 21:16:41**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was this visit performed? | Yes ☑<br>No ☐ |
| Visit date (dd MMM yyyy) | 11 NOV 2020 |
| Was visit performed at the participant's home or at the clinic? | Home ☐<br>Clinic ☑ |
| Folder OID | VISIT3 |



FDA-CBER-2022-1614-3796016

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Data signed:** (b) (4) **19 Feb 2021 21:16:41**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| 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) | |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Physical Examination**
**Data signed:** (b) (4) **19 Feb 2021 21:16:41**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was the physical examination performed? | Yes ☐<br>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.***



FDA-CBER-2022-1614-3796018

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Immunogenicity Assessment**
**Data signed:** (b) (4) **19 Feb 2021 21:16:41**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was the sample collected? | Yes ☑ No ☐ |
| Collection date *(dd MMM yyyy)* | 11 NOV 2020 |
| Collection time *(00:00-23:59)* | 10:22 (24 HR) |
| Collection date and time (derived) | 11 NOV 2020 10:22 |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **19 Feb 2021 21:16:41**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ☑<br>No ☐ |
| Continuing Flag | 1 |



FDA-CBER-2022-1614-3796020

**US3952094**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**

| **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 ■<br>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 ■<br>Yes ☐ |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 18 NOV 2020 16:31:25 |
| Patient Cloud Open Date & Time | 15 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 19 NOV 2020 23:59 |

| **TIMEPOINT** | DAY 68 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No ☐ 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 ≥ 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 ☐ |



FDA-CBER-2022-1614-3796022

| | |
|---|---|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 23 NOV 2020 23:59 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 75 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No ■<br>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 ■<br>Yes ☐ |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 27 NOV 2020 06:46:36 |
| Patient Cloud Open Date & Time | 26 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 30 NOV 2020 23:59 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 82 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No ■<br>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 ■<br>Yes ☐ |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 03 DEC 2020 12:46:33 |
| Patient Cloud Open Date & Time | 03 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 07 DEC 2020 23:59 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 89 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No ■<br>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 ■<br>Yes ☐ |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 14 DEC 2020 15:30:40 |
| Patient Cloud Open Date & Time | 10 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 14 DEC 2020 23:59 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**

| **TIMEPOINT** | DAY 96 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No ■<br>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 ■<br>Yes ☐ |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 21 DEC 2020 08:41:02 |
| Patient Cloud Open Date & Time | 17 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 21 DEC 2020 23:59 |

| **TIMEPOINT** | DAY 103 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No ☐<br>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 ☐<br>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 ☐<br>Yes ☐ |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature ≥ 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 ☐<br>Yes ☐ |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 28 DEC 2020 23:59 |



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| **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 ☐<br>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 ☐<br>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 ☐<br>Yes ☐ |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature ≥ 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 ☐<br>Yes ☐ |



FDA-CBER-2022-1614-3796030

| | |
|---|---|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 04 JAN 2021 23:59 |

| **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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ≥ 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 ☐ |



FDA-CBER-2022-1614-3796032

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 11 JAN 2021 23:59 |

| **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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ≥ 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 ☐ |

| | |
|---|---|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 18 JAN 2021 23:59 |

| **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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ≥ 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 ☐ |



FDA-CBER-2022-1614-3796036

| | |
|---|---|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately ☐ |
| Date and time of submission | |
| Patient Cloud Open Date & Time | 21 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 25 JAN 2021 23:59 |

| **TIMEPOINT** | DAY 138 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No ☐ Yes ☐ |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No ☐ Yes ☐ |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ≥ 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 ☐ |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**

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

**US3952094**
**Folder: Cosmetic Injections and Dermal Fillers**
**Form: Cosmetic Injection_ Dermal Filler eDiary**
**Generated On: 10 Jun 2021 10:28:25**

| 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 |
|---|---|---|



FDA-CBER-2022-1614-3796040

**US3952094**
**Folder: Safety Call Day 85 (1)**
**Form: Safety Call**
**Data signed:** (b) (4) **07 Apr 2021 21:43:12**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was Contact Attempted? | Yes ■<br>No ☐ |
| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 10 DEC 2020 |
| Please select one status for the follow-up contact | Contact Made ■<br>Contact Not Made ☐ |
| Comments<br><br>*If Contact Not Made, please provide Comments* | |



FDA-CBER-2022-1614-3796041

**US3952094**
**Folder: Safety Call Day 85 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **07 Apr 2021 21:43:12**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ■<br>No ☐ |
| Continuing Flag | 1 |

**US3952094**
**Folder: Safety Call Day 119 (1)**
**Form: Safety Call**
**Data signed:** (b) (4) **08 Apr 2021 19:49:21**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was Contact Attempted? | Yes ☐<br>No ■ |
| Date of Contact or Contact Attempt *(dd MMM yyyy)* | |
| Please select one status for the follow-up contact | Contact Made ☐<br>Contact Not Made ☐ |
| Comments<br><br>*If Contact Not Made, please provide Comments* | |

**US3952094**
**Folder: Safety Call Day 119 (1)**
**Form: Continuing**
**Data signed:** (b) (4) **08 Apr 2021 19:49:21**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Is the participant continuing to the next visit? | Yes ☐<br>No ■ |
| Continuing Flag | |



FDA-CBER-2022-1614-3796044

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: COVID-19 Contact**
**Data signed:** (b) (4) **08 Apr 2021 19:48:07**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Date of Contact | 07 JAN 2021 |
| Time of Contact | 10:30 |
| Date and Time of Contact (derived) | 07 JAN 2021 10:30 |
| Type of Contact | Clinic Visit - Scheduled ☐<br>Clinical Visit - Unscheduled ☐<br>Safety Call ☐<br>Convalescent Tele-visit ■ |
| Has the subject reported symptoms of SARS-COV-2? | Yes ■<br>No ☐ |



FDA-CBER-2022-1614-3796045

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

Symptom Day

- [x] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
- [ ] Day 22
- [ ] Day 23
- [ ] Day 24
- [ ] Day 25
- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32



FDA-CBER-2022-1614-3796046

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 22 DEC 2020 |
| Assessment Not Done | False |
| O2 Saturation | ND - Not Done |
| O2 Saturation Units | % |
| Temperature | ND - Not Done |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

Symptom Day

- [ ] Day 1
- [x] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
- [ ] Day 22
- [ ] Day 23
- [ ] Day 24
- [ ] Day 25
- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 23 DEC 2020 |
| Assessment Not Done | False |
| O2 Saturation | ND - Not Done |
| O2 Saturation Units | % |
| Temperature | ND - Not Done |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |



FDA-CBER-2022-1614-3796052

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [x] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
- [ ] Day 22
- [ ] Day 23
- [ ] Day 24
- [ ] Day 25
- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 24 DEC 2020 |
| Assessment Not Done | False |
| O2 Saturation | 89 % |
| O2 Saturation Units | % |
| Temperature | 39.0 C |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |



FDA-CBER-2022-1614-3796056

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |



FDA-CBER-2022-1614-3796057

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [x] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
- [ ] Day 22
- [ ] Day 23
- [ ] Day 24
- [ ] Day 25
- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 25 DEC 2020 |
| Assessment Not Done | False |
| O2 Saturation | ND - Not Done |
| O2 Saturation Units | % |
| Temperature | ND - Not Done |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |



FDA-CBER-2022-1614-3796060

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [x] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
- [ ] Day 22
- [ ] Day 23
- [ ] Day 24
- [ ] Day 25
- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32



FDA-CBER-2022-1614-3796062

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 26 DEC 2020 |
| Assessment Not Done | False |
| O2 Saturation | ND - Not Done |
| O2 Saturation Units | % |
| Temperature | ND - Not Done |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |



FDA-CBER-2022-1614-3796064

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ■
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐



FDA-CBER-2022-1614-3796066

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 27 DEC 2020 |
| Assessment Not Done | False |
| O2 Saturation | ND - Not Done |
| O2 Saturation Units | % |
| Temperature | ND - Not Done |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [x] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
- [ ] Day 22
- [ ] Day 23
- [ ] Day 24
- [ ] Day 25
- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32



FDA-CBER-2022-1614-3796070

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 28 DEC 2020 |
| Assessment Not Done | False |
| O2 Saturation | 96 % |
| O2 Saturation Units | % |
| Temperature | 36.8 C |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |



FDA-CBER-2022-1614-3796072

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ■
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐



FDA-CBER-2022-1614-3796074

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 29 DEC 2020 |
| Assessment Not Done | False |
| O2 Saturation | ND - Not Done |
| O2 Saturation Units | % |
| Temperature | ND - Not Done |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |



FDA-CBER-2022-1614-3796076

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [x] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
- [ ] Day 22
- [ ] Day 23
- [ ] Day 24
- [ ] Day 25
- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32



FDA-CBER-2022-1614-3796078

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 30 DEC 2020 |
| Assessment Not Done | False |
| O2 Saturation | ND - Not Done |
| O2 Saturation Units | % |
| Temperature | ND - Not Done |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |



FDA-CBER-2022-1614-3796080

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32



FDA-CBER-2022-1614-3796082

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 31 DEC 2020 |
| Assessment Not Done | False |
| O2 Saturation | ND - Not Done |
| O2 Saturation Units | % |
| Temperature | ND - Not Done |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ■
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐



FDA-CBER-2022-1614-3796086

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 01 JAN 2020 |
| Assessment Not Done | False |
| O2 Saturation | ND - Not Done |
| O2 Saturation Units | % |
| Temperature | ND - Not Done |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ■
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐



FDA-CBER-2022-1614-3796090

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 02 JAN 2021 |
| Assessment Not Done | False |
| O2 Saturation | ND - Not Done |
| O2 Saturation Units | % |
| Temperature | ND - Not Done |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32



FDA-CBER-2022-1614-3796094

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 03 JAN 2021 |
| Assessment Not Done | False |
| O2 Saturation | ND - Not Done |
| O2 Saturation Units | % |
| Temperature | ND - Not Done |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32



FDA-CBER-2022-1614-3796098

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 04 JAN 2021 |
| Assessment Not Done | False |
| O2 Saturation | ND - Not Done |
| O2 Saturation Units | % |
| Temperature | ND - Not Done |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ■
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐



FDA-CBER-2022-1614-3796102

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 05 JAN 2021 |
| Assessment Not Done | False |
| O2 Saturation | ND - Not Done |
| O2 Saturation Units | % |
| Temperature | ND - Not Done |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32



FDA-CBER-2022-1614-3796106

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 06 JAN 2021 |
| Assessment Not Done | False |
| O2 Saturation | ND - Not Done |
| O2 Saturation Units | % |
| Temperature | ND - Not Done |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ■
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐



FDA-CBER-2022-1614-3796110

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 07 JAN 2021 |
| Assessment Not Done | False |
| O2 Saturation | ND - Not Done |
| O2 Saturation Units | % |
| Temperature | 98.6 F |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [x] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
- [ ] Day 22
- [ ] Day 23
- [ ] Day 24
- [ ] Day 25
- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32



FDA-CBER-2022-1614-3796114

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 08 JAN 2021 |
| Assessment Not Done | False |
| O2 Saturation | 96 % |
| O2 Saturation Units | % |
| Temperature | 37.8 C |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |



FDA-CBER-2022-1614-3796116

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |



FDA-CBER-2022-1614-3796117

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [x] Day 19
- [ ] Day 20
- [ ] Day 21
- [ ] Day 22
- [ ] Day 23
- [ ] Day 24
- [ ] Day 25
- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32



FDA-CBER-2022-1614-3796118

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 09 JAN 2021 |
| Assessment Not Done | False |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | ND - Not Done |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |



FDA-CBER-2022-1614-3796120

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ■
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 10 JAN 2021 |
| Assessment Not Done | False |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | 102.2 F |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |



FDA-CBER-2022-1614-3796124

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32



FDA-CBER-2022-1614-3796126

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 11 JAN 2021 |
| Assessment Not Done | False |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | 98 F |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

Symptom Day

Day 1 ☐
Day 2 ☐
Day 3 ☐
Day 4 ☐
Day 5 ☐
Day 6 ☐
Day 7 ☐
Day 8 ☐
Day 9 ☐
Day 10 ☐
Day 11 ☐
Day 12 ☐
Day 13 ☐
Day 14 ☐
Day 15 ☐
Day 16 ☐
Day 17 ☐
Day 18 ☐
Day 19 ☐
Day 20 ☐
Day 21 ☐
Day 22 ■
Day 23 ☐
Day 24 ☐
Day 25 ☐
Day 26 ☐
Day 27 ☐
Day 28 ☐
Day 29 ☐
Day 30 ☐
Day 31 ☐
Day 32 ☐



FDA-CBER-2022-1614-3796130

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 12 JAN 2021 |
| Assessment Not Done | False |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | 98.6 F |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ■
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐



FDA-CBER-2022-1614-3796134

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 13 JAN 2021 |
| Assessment Not Done | True |
| O2 Saturation | 98 % |
| O2 Saturation Units | % |
| Temperature | 39.1 C |
| Chills | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |

| | |
|---|---|
| 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 ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

Symptom Day

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28
Day 29
Day 30
Day 31
Day 32



FDA-CBER-2022-1614-3796138

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 14 JAN 2021 |
| Assessment Not Done | False |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | ND - Not Done |
| Chills | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ■ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ■ |
| | Not Done ☐ |
| Difficulty Breathing | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Muscle Aches (Myalgia) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Body Aches | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Headache | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Taste | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| New Loss of Smell | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |



FDA-CBER-2022-1614-3796141

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ■
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐



FDA-CBER-2022-1614-3796142

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 15 JAN 2021 |
| Assessment Not Done | False |
| O2 Saturation | 85 % |
| O2 Saturation Units | % |
| Temperature | 97.8 F |
| Chills | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ■<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ■ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |



FDA-CBER-2022-1614-3796144

| | |
|---|---|
| Nasal Congestion | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Runny Nose (Rhinorrhea) | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Nausea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Vomiting | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Diarrhea | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Sore Throat | None ■<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32



FDA-CBER-2022-1614-3796146

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 16 JAN 2021 |
| Assessment Not Done | True |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | |
| Chills | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |

| | |
|---|---|
| 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 ☐ |

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ■
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐



FDA-CBER-2022-1614-3796150

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 17 JAN 2021 |
| Assessment Not Done | True |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | |
| Chills | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |

| | |
|---|---|
| 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 ☐ |

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ■
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐



FDA-CBER-2022-1614-3796154

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 18 JAN 2021 |
| Assessment Not Done | True |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | |
| Chills | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |

| | |
|---|---|
| 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 ☐ |



FDA-CBER-2022-1614-3796157

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ■
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐



FDA-CBER-2022-1614-3796158

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 19 JAN 2021 |
| Assessment Not Done | True |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | |
| Chills | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |



FDA-CBER-2022-1614-3796160

| | |
|---|---|
| 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 ☐ |

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32



FDA-CBER-2022-1614-3796162

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 20 JAN 2021 |
| Assessment Not Done | True |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | |
| Chills | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |

| | |
|---|---|
| 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 ☐ |

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32



FDA-CBER-2022-1614-3796166

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 21 JAN 2021 |
| Assessment Not Done | True |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | |
| Chills | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |

| | |
|---|---|
| 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 ☐ |



FDA-CBER-2022-1614-3796169

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32



FDA-CBER-2022-1614-3796170

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 22 JAN 2021 |
| Assessment Not Done | True |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | |
| Chills | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |

| | |
|---|---|
| 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 ☐ |



FDA-CBER-2022-1614-3796173

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
- [ ] Day 22
- [ ] Day 23
- [ ] Day 24
- [ ] Day 25
- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32



FDA-CBER-2022-1614-3796174

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Day 33 ■ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 23 JAN 2021 |
| Assessment Not Done | True |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | |
| Chills | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |

| | |
|---|---|
| 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 ☐ |

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32



FDA-CBER-2022-1614-3796178

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ■ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 24 JAN 2012 |
| Assessment Not Done | True |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | |
| Chills | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |



FDA-CBER-2022-1614-3796179

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |



FDA-CBER-2022-1614-3796180

| | |
|---|---|
| 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 ☐ |



FDA-CBER-2022-1614-3796181

Symptom Day

- ☐ Day 1
- ☐ Day 2
- ☐ Day 3
- ☐ Day 4
- ☐ Day 5
- ☐ Day 6
- ☐ Day 7
- ☐ Day 8
- ☐ Day 9
- ☐ Day 10
- ☐ Day 11
- ☐ Day 12
- ☐ Day 13
- ☐ Day 14
- ☐ Day 15
- ☐ Day 16
- ☐ Day 17
- ☐ Day 18
- ☐ Day 19
- ☐ Day 20
- ☐ Day 21
- ☐ Day 22
- ☐ Day 23
- ☐ Day 24
- ☐ Day 25
- ☐ Day 26
- ☐ Day 27
- ☐ Day 28
- ☐ Day 29
- ☐ Day 30
- ☐ Day 31
- ☐ Day 32



FDA-CBER-2022-1614-3796182

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ■ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ☐ |
| Date | 25 JAN 2021 |
| Assessment Not Done | True |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | |
| Chills | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |



FDA-CBER-2022-1614-3796184

| | |
|---|---|
| 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 ☐ |

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32



FDA-CBER-2022-1614-3796186

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ■<br>Day 37 ☐<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 26 JAN 2021 |
| Assessment Not Done | False |
| O2 Saturation | 91 % |
| O2 Saturation Units | % |
| Temperature | 37.8 C |
| Chills | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Cough | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Shortness of Breath | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Difficulty Breathing | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

| | |
|---|---|
| | Not Done ■ |
| Fatigue | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Muscle Aches (Myalgia) | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Body Aches | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Headache | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| New Loss of Taste | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| New Loss of Smell | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |

| | |
|---|---|
| Nasal Congestion | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Runny Nose (Rhinorrhea) | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Nausea | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Vomiting | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Diarrhea | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Sore Throat | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32



FDA-CBER-2022-1614-3796190

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ■<br>Day 38 ☐<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 27 JAN 2021 |
| Assessment Not Done | True |
| O2 Saturation | 99 % |
| O2 Saturation Units | % |
| Temperature | 36.9 C |
| Chills | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Cough | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Shortness of Breath | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ☐ |
| Difficulty Breathing | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |

| | |
|---|---|
| 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 ☐ |

Symptom Day

- ☐ Day 1
- ☐ Day 2
- ☐ Day 3
- ☐ Day 4
- ☐ Day 5
- ☐ Day 6
- ☐ Day 7
- ☐ Day 8
- ☐ Day 9
- ☐ Day 10
- ☐ Day 11
- ☐ Day 12
- ☐ Day 13
- ☐ Day 14
- ☐ Day 15
- ☐ Day 16
- ☐ Day 17
- ☐ Day 18
- ☐ Day 19
- ☐ Day 20
- ☐ Day 21
- ☐ Day 22
- ☐ Day 23
- ☐ Day 24
- ☐ Day 25
- ☐ Day 26
- ☐ Day 27
- ☐ Day 28
- ☐ Day 29
- ☐ Day 30
- ☐ Day 31
- ☐ Day 32



FDA-CBER-2022-1614-3796194

| | |
|---|---|
| | Day 33 ☐<br>Day 34 ☐<br>Day 35 ☐<br>Day 36 ☐<br>Day 37 ☐<br>Day 38 ■<br>Day 39 ☐<br>Day 40 ☐ |
| Date | 28 JAN 2012 |
| Assessment Not Done | False |
| O2 Saturation | ND - Not Done |
| O2 Saturation Units | % |
| Temperature | ND - Not Done |
| Chills | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Cough | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Shortness of Breath | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Difficulty Breathing | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ■ |
| Fatigue | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Muscle Aches (Myalgia) | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Body Aches | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Headache | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| New Loss of Taste | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| New Loss of Smell | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |

| | |
|---|---|
| Nasal Congestion | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Runny Nose (Rhinorrhea) | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Nausea | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Vomiting | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Diarrhea | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |
| Sore Throat | None ☐<br>Mild ☐<br>Moderate ☐<br>Severe ☐<br>Not Done ■ |

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32



FDA-CBER-2022-1614-3796198

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ■ |
| | Day 40 ☐ |
| Date | 29 JAN 2021 |
| Assessment Not Done | True |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | |
| Chills | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |

| | |
|---|---|
| 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 ☐ |



FDA-CBER-2022-1614-3796201

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32



FDA-CBER-2022-1614-3796202

| | |
|---|---|
| | Day 33 ☐ |
| | Day 34 ☐ |
| | Day 35 ☐ |
| | Day 36 ☐ |
| | Day 37 ☐ |
| | Day 38 ☐ |
| | Day 39 ☐ |
| | Day 40 ■ |
| Date | 30 JAN 2021 |
| Assessment Not Done | True |
| O2 Saturation | |
| O2 Saturation Units | |
| Temperature | |
| Chills | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Cough | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Shortness of Breath | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Difficulty Breathing | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| | Not Done ☐ |
| Fatigue | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Muscle Aches (Myalgia) | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Body Aches | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| Headache | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Taste | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |
| New Loss of Smell | None ☐ |
| | Mild ☐ |
| | Moderate ☐ |
| | Severe ☐ |
| | Not Done ☐ |



FDA-CBER-2022-1614-3796204

| | |
|---|---|
| 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 ☐ |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: COVID Diagnostic Test**
**Data signed:** (b) (4) **09 Apr 2021 20:15:44**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Date of Visit | 24 DEC 2020 |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR? | Yes ■<br>No ☐ |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR? | Yes ■<br>No ☐ |
| Date of Test | 24 DEC 2020 |
| Type of Test Performed | Nasopharyngeal Swab ■<br>Nasal Swab ☐<br>Saliva Test ☐<br>Other ☐ |
| Other, specify | |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes ■<br>No ☐ |
| If yes, provide lab information below | |
| Lab/ Institution Test Performed | WASHINGTON HOSPITAL CENTER |
| CLIA Certified? | Yes ■<br>No ☐ |
| COVID-19 Positive (CSA Programming Field Only) | 1 |



FDA-CBER-2022-1614-3796206

| | |
|---|---|
| Did the subject have Respiratory Rates ≥ 30 per Minute? | Yes ■ No ☐ |
| If Yes, provide: | |
| Start Date | 13 JAN 2021 |
| End Date | 30 JAN 2021 |
| Respiratory Rate | 46 /minute |
| 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 ≤ 93% on room air at sea level? | Yes ■ No ☐ |
| If Yes, provide: | |
| Start Date | 19 JAN 2021 |
| End Date | 30 JAN 2021 |
| Oxygen Saturation | 74 % |
| 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 | 19 JAN 2021 |
| Did the subject have Acute Respiratory Distress Syndrome (ARDS)? | Yes ■ No ☐ |
| Start Date | 19 JAN 2021 |

**If Yes to either Did subject require any of the following:**

| | |
|---|---|
| **Ventilator Support:** | |
| High-Flow Oxygen? | Yes ■<br>No ☐ |
| Start Date | 13 JAN 2021 |
| End Date | 19 JAN 2021 |
| Non-Invasive Ventilation? | Yes ■<br>No ☐ |
| Start Date | 24 DEC 2020 |
| End Date | 13 JAN 2021 |
| Mechanical Ventilation? | Yes ■<br>No ☐ |
| Start Date | 19 JAN 2021 |
| End Date | 30 JAN 2021 |
| ECMO? | Yes ☐<br>No ☐ |
| Start Date | |
| End Date | |
| **Evidence of Shock:** | |
| Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg | Yes ☐<br>No ☐ |
| Start Date | |
| End Date | |
| Evidence of Shock Requires Vasopressors | Yes ☐<br>No ☐ |
| Start Date | |
| End Date | |
| Acute Renal Dysfunction? | Yes ☐<br>No ☐ |
| Start Date | |



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| | |
|---|---|
| Hepatic Dysfunction? | Yes ☐ No ☐ |
| Start Date | |
| Neurologic Dysfunction? | Yes ☐ No ☐ |
| Start Date | |

**Evidence of Pneumonia:**

| | |
|---|---|
| Clinical Evidence | Yes ■ No ☐ |
| Date of Assessment | 24 DEC 2020 |
| Radiographical Evidence | Yes ■ No ☐ |
| Date of Assessment | 24 DEC 2020 |

| | |
|---|---|
| Admission to an intensive care unit due to SARS-CoV-2 | Yes ■ No ☐ |
| Start Date | 19 JAN 2021 |
| End Date | 30 JAN 2021 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Generate Next COVID-19 Assessment**
**Data signed:** (b) (4) **08 Apr 2021 19:49:20**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Generate Next COVID-19 Assessment | Yes ☐<br>No ■ |



FDA-CBER-2022-1614-3796210

**US3952094**
**Folder: Illness Visit (1)**
**Form: Saliva Collection**
**Generated On: 10 Jun 2021 10:28:25**

| Visit | Was Saliva Collected? | Date of Collection |
|---|---|---|
| Day 3 | | |
| Day 5 | | |
| Day 7 | | |
| Day 9 | | |
| Day 14 | | |
| Day 21 | | |
| Day 28 | | |



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**US3952094**
**Folder: Illness Visit Day 1 (1)**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was this visit performed? | Yes ☐<br>No ☐ |
| Visit date (dd MMM yyyy) | |
| Was visit performed at the participant's home or at the clinic? | Home ☐<br>Clinic ☐ |
| Folder OID | |



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**US3952094**
**Folder: Illness Visit Day 1 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| 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) | |

**US3952094**
**Folder: Illness Visit Day 1 (1)**
**Form: Physical Examination**
**Generated On: 10 Jun 2021 10:28:25**

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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| | |
|---|---|
| Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection? | Yes ☐<br>No ☐<br>NA (COVID-19 Negative) ☐ |
| Date of Collection | _____ |

**US3952094**
**Folder: Convalescence Visit Day 28 (1)**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was this visit performed? | Yes ☐<br>No ☐ |
| Visit date (dd MMM yyyy) | |
| Was visit performed at the participant's home or at the clinic? | Home ☐<br>Clinic ☐ |
| Folder OID | |

**US3952094**
**Folder: Convalescence Visit Day 28 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| 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) | |

**US3952094**
**Folder: Convalescence Visit Day 28 (1)**
**Form: Physical Examination**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was the physical examination performed? | Yes ☐<br>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.***

| | |
|---|---|
| Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection? | Yes ☐<br>No ☐<br>NA (COVID-19 Negative) ☐ |
| Date of Collection | _____ |

**US3952094**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was this visit performed? | Yes ☐<br>No ☐ |
| Visit date (dd MMM yyyy) | |
| Was visit performed at the participant's home or at the clinic? | Home ☐<br>Clinic ☐ |
| Folder OID | |



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**US3952094**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Unblinding**
**Generated On: 10 Jun 2021 10:28:25**

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

| | |
|---|---|
| Was the sample collected? | Yes ☐<br>No ☐ |
| Collection date *(dd MMM yyyy)* | |
| Collection time *(00:00-23:59)* | |
| Collection date and time (derived) | |

**US3952094**
**Folder: Participant Decision Visit / OL-D1 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (Single)**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Was the sample collected? | Yes ☐<br>No ☐ |
| Collection date *(dd MMM yyyy)* | |
| Collection time *(00:00 - 23:59)* | |
| Collection Date and Time (derived) | |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events Summary**
**Data signed:** (b) (4) **08 Apr 2021 19:10:00**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Did the participant experience any adverse events? | Yes ■<br>No ☐ |

**If Yes, enter details on the Adverse Events form.**



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**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:49**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| AEID | USA-US215-2021-MRNA-1273-P30 1000001 |
| Adverse event | SARS-COV-2 INFECTION |
| Was this a medically-attended AE? | Yes ■<br>No ☐ |
| Was this a Solicited Adverse Reaction? | Yes ☐<br>No ■ |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes ■<br>No ☐ |
| Start date *(dd MMM yyyy)* | 24 DEC 2020 |
| Start time *(00:00-23:59)* | |
| AE start date and time (derived) | |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, end date *(dd MMM yyyy)* | 30 JAN 2021 |
| End time *(00:00-23:59)* | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild ☐<br>Grade 2/Moderate ☐<br>Grade 3/Severe ☐<br>Grade 4 ■ |
| Is the adverse event serious? | Yes ■<br>No ☐ |
| AE is serious due To (check all that apply) | |
| Death | True |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date *(dd MMM yyyy)* | 24 DEC 2020 |
| Hospital Discharge Date *(dd MMM yyyy)* | 30 JAN 2021 |
| Admitted to ICU? | Yes ■<br>No ☐<br>Unknown ☐ |



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| | |
|---|---|
| Number of Days in ICU | 17 |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related ■<br>Related ☐<br>Not Applicable ☐ |
| Relationship to Study Procedure | Not Related ■<br>Related ☐<br>Not Applicable ☐ |
| Action taken with investigational product | None ☐<br>Dose Delayed ☐<br>Investigational Product Withdrawn ☐<br>Not Applicable ■ |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | True |
| Outcome | Fatal ■<br>Not Recovered/Not Resolved ☐<br>Recovered/Resolved ☐<br>Recovered/Resolved with Sequelae ☐<br>Recovering/Resolving ☐<br>Unknown ☐ |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |

PATIENT WAS ADMITTED TO THE HOSPITAL ON 24DEC2020 WITH SYMPTOMS OF LOSS OF SMELL, FEVER, RUNNY NOSE. TREATED WITH STEROIDS. SUBJECT GIVEN SUPPLEMENTAL OXYGEN.

PRELIMINARY REVIEW OF MEDICAL RECORD INDICATES COVID + ARDS WITH DECLINING RESPIRATORY STATUS. SUBJECT WAS INTUBATED AND EXPIRED ON 30JAN2021. DISCHARGE/DEATH SUMMARY HAS BEEN REQUESTED. FURTHER DETAIL WILL BE PROVIDED UPON RECEIPT OF SUCH.

MEDICAL RECORDS REVIEWED. SUBJECT PRESENTED TO ER ON 24DEC2020 WITH COUGH, SHORTNESS OF BREATH AND FEVER. WITH SHORTNESS OF BREATH HE WAS ALSO EXPERIENCING SOME CHEST PAIN. HE WAS HYPOXIC (89% OXYGEN SATURATION) WITH A HR OF 108 AND RR OF 24. HE REQUIRED 2 L OF NASAL CANNULA TO MAINTAIN ADEQUATE OXYGENATION. HE WAS GIVEN TYLENOL FOR

FEVER, AND DEXAMETHASONE WAS STARTED AS COVID WAS SUSPECTED. CHEST XRAY AND CT WERE CONSISTENT WITH COVID. HE HAD A NEGATIVE CARDIAC WORK UP FOR HIS CHEST PAIN (NEGATIVE TROPONIN AND NO ISCHEMIA ON EKG).

TESTING FOR CORONAVIRUS ON 24DEC2021 WAS POSITIVE. NEGATIVE TEST RESULTS FOR INFLUENZA A/B AND RSV.

OVER THE COURSE OF HOSPITALIZATION SUBJECT NEEDED UP TO 15L/MIN OXYGEN VIA NRB. HE COMPLETED A 5 DAY COURSE OF REMDESIVIR AND A 10 DAY COURSE OF DEXAMETHASONE. WITH WORSENING SHORTNESS OF BREATH AND TACHYPNEA TO 40S AND WORSENING CHEST XRAY, INFECTIOUS DISEASE BEGAN VANCOMYCIN 750MG IV Q12H AND ZOSYN 4.5 G IV Q6H FOR NEW SEPSIS OF HOSPITAL ACQUIRED PNEUMONIA. HE WAS TRIAGED TO THE SICU ON 13JAN2021 FOR ACUTE HYPOXIC RESPIRATORY INSUFFICIENCY REQUIRING

HFNC 60L, 100%.

HOSPITAL COURSE WAS COMPLICATED BY C DIFF. SUBJECT RECEIVED VANCOMYCIN.

SUBJECT INTUBATED ON 19JAN2021. 27JAN2021, BRONCHOSCOPY PERFORMED EMERGENTLY FOR POTENTIAL AIRWAY OCCLUSION. HOWEVER AIRWAYS WERE FOUND TO BE PATENT.

PALLIATIVE CARE WAS CONSULTED ON 26JAN2021. PATIENT EXPIRED ON 30JAN2021 AT 0207.

SUBJECT ALSO RECEIVED BLOOD TRANSFUSION ON 28JAN2021 AND CT ANGIOGRAPHY PULMONARY ON 05JAN2021.

| | |
|---|---|
| Serious Adverse Event Derived (CSA Programming Field Ony) | 1 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | 1 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:49**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| AEID | |
| Adverse event | CLOSTRIDIUM DIFFICILE |
| Was this a medically-attended AE? | Yes ☐<br>No ■ |
| Was this a Solicited Adverse Reaction? | Yes ☐<br>No ■ |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes ☐<br>No ■ |
| Start date *(dd MMM yyyy)* | 03 JAN 2021 |
| Start time *(00:00-23:59)* | |
| AE start date and time (derived) | |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, end date *(dd MMM yyyy)* | 17 JAN 2021 |
| End time *(00:00-23:59)* | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild ☐<br>Grade 2/Moderate ■<br>Grade 3/Severe ☐<br>Grade 4 ☐ |
| Is the adverse event serious? | Yes ☐<br>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 ☐<br>No ☐<br>Unknown ☐ |
| Number of Days in ICU | |



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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 ■<br>Related ☐<br>Not Applicable ☐ |
| Relationship to Study Procedure | Not Related ■<br>Related ☐<br>Not Applicable ☐ |
| Action taken with investigational product | None ☐<br>Dose Delayed ☐<br>Investigational Product Withdrawn ☐<br>Not Applicable ■ |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal ☐<br>Not Recovered/Not Resolved ☐<br>Recovered/Resolved ■<br>Recovered/Resolved with Sequelae ☐<br>Recovering/Resolving ☐<br>Unknown ☐ |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Ony) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:49**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| AEID | |
| Adverse event | HOSPITAL ACQUIRED PNEUMONIA |
| Was this a medically-attended AE? | Yes ☐<br>No ■ |
| Was this a Solicited Adverse Reaction? | Yes ☐<br>No ■ |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes ☐<br>No ■ |
| Start date *(dd MMM yyyy)* | 13 JAN 2021 |
| Start time *(00:00-23:59)* | |
| AE start date and time (derived) | |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, end date *(dd MMM yyyy)* | 22 JAN 2021 |
| End time *(00:00-23:59)* | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild ☐<br>Grade 2/Moderate ■<br>Grade 3/Severe ☐<br>Grade 4 ☐ |
| Is the adverse event serious? | Yes ☐<br>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 ☐<br>No ☐<br>Unknown ☐ |



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| | |
|---|---|
| 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 ■<br>Related ☐<br>Not Applicable ☐ |
| Relationship to Study Procedure | Not Related ■<br>Related ☐<br>Not Applicable ☐ |
| Action taken with investigational product | None ☐<br>Dose Delayed ☐<br>Investigational Product Withdrawn ☐<br>Not Applicable ■ |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal ☐<br>Not Recovered/Not Resolved ☐<br>Recovered/Resolved ■<br>Recovered/Resolved with Sequelae ☐<br>Recovering/Resolving ☐<br>Unknown ☐ |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Ony) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination Summary**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Were any prior/concomitant medications and/or vaccinations taken? | Yes ■<br>No ☐ |

**If Yes, please complete Prior/Concomitant Medication and Vaccination form.**

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:49**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Name of Medication | LISINOPRIL |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | HYPERTENSION |
| Dose per administration | 20 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ■<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |



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| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | UN UNK 2010 |
| Start date completely unknown | False |
| Ongoing? | Yes ■<br>No ☐ |
| If not Ongoing, End date *(dd MMM yyyy)* | |
| Was this medication taken for solicited event? | Yes ☐<br>No ■ |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐<br>803 ☐<br>804 ■ |

| | |
|---|---|
| Name of Medication | JANUMET |
| Prophylaxis | Yes ☐ No ■ |
| Indication | DIABETES |
| Dose per administration | 50/1000 |
| 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 ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | UN UNK 2019 |
| Start date completely unknown | False |
| Ongoing? | Yes ■<br>No ☐ |
| If not Ongoing, End date *(dd MMM yyyy)* | |
| Was this medication taken for solicited event? | Yes ☐<br>No ■ |
| Separate Dosage Number (derived) | 2 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐<br>803 ☐<br>804 ■ |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:49**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Name of Medication | SIMVASTATIN |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | HIGH CHOLESTEROL |
| Dose per administration | 20 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ■<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |



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| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | UN UNK 2015 |
| Start date completely unknown | False |
| Ongoing? | Yes ■<br>No ☐ |
| If not Ongoing, End date *(dd MMM yyyy)* | |
| Was this medication taken for solicited event? | Yes ☐<br>No ■ |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐<br>803 ☐<br>804 ■ |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:49**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Name of Medication | MELOXICAM |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | LEFT KNEE PAIN |
| Dose per administration | 7.5 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ■<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |



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| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | UN MAR 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ■ |
| | No ☐ |
| If not Ongoing, End date *(dd MMM yyyy)* | |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ■ |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:49**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Name of Medication | INFLUENZA VACCINE |
| Prophylaxis | Yes ■<br>No ☐ |
| Indication | FLU PREVENTION |
| Dose per administration | 0.5 |
| Dose unit | mg ☐<br>ug ☐<br>mL ■<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ■<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ☐<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ■<br>Respiratory (Inhalation) ☐<br>Intralesional ☐<br>Intraperiteoneal ☐<br>Nasal ☐<br>Vaginal ☐<br>Rectal ☐<br>Intravenous ☐<br>Intravenous Bolus ☐<br>Intravenous Drip ☐<br>Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | 23 AUG 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐<br>No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 23 AUG 2020 |
| Was this medication taken for solicited event? | Yes ☐<br>No ■ |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐<br>803 ☐<br>804 ■ |

| | |
|---|---|
| Name of Medication | CORTISONE INJECTION |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | LEFT KNEE PAIN |
| Dose per administration | 1 |
| Dose unit | mg ☐<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ■ |
| If dose unit is Other, specify | INJECTION |
| Frequency | once daily ☐<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ■<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ☐<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ■ |
| If route of administration is Other, specify | INTRA-ARTICULAR |
| Start date *(dd MMM yyyy)* | 09 OCT 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐ |
| | No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 09 OCT 2020 |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | |
| Interval Dosage Unit Number (derived) | |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ☐ |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:49**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Name of Medication | REMDESIVIR |
| Prophylaxis | Yes ☐ |
| | No ■ |
| Indication | SARS-COV-2 INFECTION |
| Dose per administration | 100 |
| 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 ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ■ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | 25 DEC 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐ |
| | No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 29 DEC 2020 |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ■ |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:49**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Name of Medication | DEXAMETHASONE |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | SARS-COV-2 INFECTION |
| Dose per administration | 6 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ■<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ☐<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ■ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | 25 DEC 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐ |
| | No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 03 JAN 2021 |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ■ |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:49**
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| | |
|---|---|
| Name of Medication | VANCOMYCIN |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | HOSPITAL ACQUIRED PNEUMONIA |
| Dose per administration | 750 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ☐<br>twice daily ■<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ☐<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐ |

| | |
|---|---|
| | Intraocular ☐ |
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ■ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | 13 JAN 2021 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐ |
| | No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 22 JAN 2021 |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | 2 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ■ |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:49**
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| | |
|---|---|
| Name of Medication | ZOSYN |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | HOSPITAL ACQUIRED PNEUMONIA |
| Dose per administration | 4.5 |
| Dose unit | mg ☐<br>ug ☐<br>mL ☐<br>g ■<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ☐<br>twice daily ☐<br>three times daily ☐<br>four times daily ■<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ☐<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐ |

| | |
|---|---|
| | Intraocular ☐ |
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ■ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | 13 JAN 2021 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐ |
| | No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 22 JAN 2021 |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | 4 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ■ |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:49**
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| | |
|---|---|
| Name of Medication | VANCOMYCIN |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | CLOSTRIDIUM DIFFICILE |
| Dose per administration | 125 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ☐<br>twice daily ☐<br>three times daily ☐<br>four times daily ■<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |



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| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | 04 JAN 2021 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐ |
| | No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 17 JAN 2021 |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | 4 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ■ |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:49**
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| | |
|---|---|
| Name of Medication | AZITHROMYCIN |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | SARS-COV-2 INFECTION |
| Dose per administration | 250 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ■<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | 25 DEC 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐ |
| | No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 29 DEC 2020 |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ■ |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:49**
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| | |
|---|---|
| Name of Medication | CEFTRIAXONE |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | SARS-COV-2 INFECTION |
| Dose per administration | 1 |
| Dose unit | mg ☐<br>ug ☐<br>mL ☐<br>g ■<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ■<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ☐<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ■ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | 25 DEC 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐ |
| | No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 25 DEC 2020 |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ■ |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:49**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Name of Medication | ENOXAPARIN |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | SARS-COV-2 INFECTION |
| Dose per administration | 40 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ■<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ☐<br>Topical ☐<br>Subcutaneous ■<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | 25 DEC 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐ |
| | No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 30 JAN 2021 |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ■ |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:49**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Name of Medication | DEXAMETHASONE |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | SARS-COV-2 INFECTION |
| Dose per administration | 6 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ☐<br>twice daily ☐<br>three times daily ☐<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ■<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ☐<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ■ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | 25 DEC 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐ |
| | No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 25 DEC 2020 |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | |
| Interval Dosage Unit Number (derived) | |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ☐ |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:49**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Name of Medication | TYLENOL [ACETAMINOPHEN] |
| Prophylaxis | Yes ☐<br>No ■ |
| Indication | SARS-COV-2 INFECTION |
| Dose per administration | 1000 |
| Dose unit | mg ■<br>ug ☐<br>mL ☐<br>g ☐<br>IU ☐<br>tablet ☐<br>capsule ☐<br>puff ☐<br>Other ☐ |
| If dose unit is Other, specify | |
| Frequency | once daily ☐<br>twice daily ☐<br>three times daily ■<br>four times daily ☐<br>every other day ☐<br>every week ☐<br>every month ☐<br>as needed ☐<br>once ☐<br>unknown ☐<br>other ☐ |
| If frequency is Other, specify | |
| Route of administration | Oral ■<br>Topical ☐<br>Subcutaneous ☐<br>Transdermal ☐<br>Intraocular ☐ |

| | |
|---|---|
| | Intramuscular ☐ |
| | Respiratory (Inhalation) ☐ |
| | Intralesional ☐ |
| | Intraperiteoneal ☐ |
| | Nasal ☐ |
| | Vaginal ☐ |
| | Rectal ☐ |
| | Intravenous ☐ |
| | Intravenous Bolus ☐ |
| | Intravenous Drip ☐ |
| | Other ☐ |
| If route of administration is Other, specify | |
| Start date *(dd MMM yyyy)* | 24 DEC 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes ☐ |
| | No ■ |
| If not Ongoing, End date *(dd MMM yyyy)* | 30 JAN 2021 |
| Was this medication taken for solicited event? | Yes ☐ |
| | No ■ |
| Separate Dosage Number (derived) | 3 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 ☐ |
| | 803 ☐ |
| | 804 ■ |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures Summary**
**Data signed:** (b) (4) **08 Apr 2021 19:48:07**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Were any concomitant procedures performed? | Yes ■<br>No ☐ |

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



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**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures**
**Data signed:** (b) (4) **16 Apr 2021 16:32:50**
**Generated On: 10 Jun 2021 10:28:25**

| Procedure/Surgery date *(dd MMM yyyy)* | Procedure/Surgery | Indication | If indication is Other, specify |
|---|---|---|---|
| 25 DEC 2020 | CT OF CHEST | Adverse Event | |
| 19 JAN 2021 | INTUBATION | Adverse Event | |
| 27 JAN 2021 | BRONCHOSCOPY | Adverse Event | |
| 28 JAN 2021 | BLOOD TRANSFUSION | Adverse Event | |
| 05 JAN 2021 | CT ANGIOGRAPHY PULMONARY | Adverse Event | |
| 24 DEC 2020 | X-RAY OF CHEST | Adverse Event | |
| 13 JAN 2021 | X-RAY OF THE CHEST | Adverse Event | |
| 26 JAN 2021 | X-RAY OF THE CHEST | Adverse Event | |



FDA-CBER-2022-1614-3796268

**US3952094**
**Folder: End of Study (1)**
**Form: Dosing Discontinuation**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Date of dosing discontinuation (dd MMM yyyy) | |
| Primary reason for dosing discontinuation | AE (specify) ☐<br>SAE (specify) ☐<br>Death ☐<br>Lost To Follow-up ☐<br>Physician decision (specify) ☐<br>Pregnancy ☐<br>Protocol deviation (specify) ☐<br>Study Terminated By Sponsor ☐<br>Withdrawal of consent by participant (specify) ☐<br>Due to SARS-COV-2 ☐<br>Other ☐ |
| If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify | |

**US3952094**
**Folder: End of Study (1)**
**Form: End of Study / Study Discontinuation**
**Data signed:** (b) (4) **16 Apr 2021 16:32:53**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| Date of study discontinuation/completion *(dd MMM yyyy)* | 30 JAN 2021 |
| Reason for discontinuation | AE (specify) ☐<br>SAE (specify) ☐<br>Complete ☐<br>Death ■<br>Lost To Follow-up ☐<br>Physician decision (specify) ☐<br>Pregnancy ☐<br>Protocol deviation (specify) ☐<br>Study Terminated By Sponsor ☐<br>Withdrawal of consent by participant (specify) ☐<br>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 ■<br>Unknown ☐<br>Other ☐ |
| If main cause of death is Other, specify | |
| Date of death *(dd MMM yyyy)* | 30 JAN 2021 |
| Was autopsy performed? | Yes ☐<br>No ■<br>Unknown ☐ |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Data signed:** (b) (4) **16 Apr 2021 16:32:53**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| SAEID | USA-US215-2021-MRNA-1273-P301000001 |
| Serious | Yes ■ No ☐ |
| Death | Yes ■ No ☐ |
| Life threatening | Yes ☐ No ■ |
| Requires inpatient or prolongation of existing Hospitalization | Yes ■ No ☐ |
| Persistent or significant disability or incapacity | Yes ☐ No ■ |
| Congenital anomaly or birth defect | Yes ☐ No ■ |
| Other medically important event | Yes ☐ No ■ |
| Investigator's First Name | MIMI |
| Investigator's Last Name | VAN DER LEDEN |
| Site Address: Street | 15201 SHADY GROVE DR |
| Site Address: City | ROCKVILLE |
| Site Address: State | |
| Site Address: Postal Code | 20850 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 9 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (1)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:53**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| SAEID | USA-US215-2021-MRNA-1273-P301000001 |
| Serious | Yes ■ No ☐ |
| Death | Yes ■ No ☐ |
| Life threatening | Yes ☐ No ■ |
| Requires inpatient or prolongation of existing Hospitalization | Yes ■ No ☐ |
| Persistent or significant disability or incapacity | Yes ☐ No ■ |
| Congenital anomaly or birth defect | Yes ☐ No ■ |
| Other medically important event | Yes ☐ No ■ |
| Investigator's First Name | MIMI |
| Investigator's Last Name | VAN DER LEDEN |
| Site Address: Street | 15201 SHADY GROVE DR |
| Site Address: City | ROCKVILLE |
| Site Address: State | |
| Site Address: Postal Code | 20850 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 9 |
| Date of submission (Pre-filled from custom function) | 04/JAN/2021 18:28 |
| **Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.** | True |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (2)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:53**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| SAEID | USA-US215-2021-MRNA-1273-P301000001 |
| Serious | Yes ■ No ☐ |
| Death | Yes ■ No ☐ |
| Life threatening | Yes ☐ No ■ |
| Requires inpatient or prolongation of existing Hospitalization | Yes ■ No ☐ |
| Persistent or significant disability or incapacity | Yes ☐ No ■ |
| Congenital anomaly or birth defect | Yes ☐ No ■ |
| Other medically important event | Yes ☐ No ■ |
| Investigator's First Name | MIMI |
| Investigator's Last Name | VAN DER LEDEN |
| Site Address: Street | 15201 SHADY GROVE DR |
| Site Address: City | ROCKVILLE |
| Site Address: State | |
| Site Address: Postal Code | 20850 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 9 |
| Date of submission (Pre-filled from custom function) | 07/JAN/2021 11:57 |
| **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 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (3)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:53**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| SAEID | USA-US215-2021-MRNA-1273-P301000001 |
| Serious | Yes ■ No ☐ |
| Death | Yes ■ No ☐ |
| Life threatening | Yes ☐ No ■ |
| Requires inpatient or prolongation of existing Hospitalization | Yes ■ No ☐ |
| Persistent or significant disability or incapacity | Yes ☐ No ■ |
| Congenital anomaly or birth defect | Yes ☐ No ■ |
| Other medically important event | Yes ☐ No ■ |
| Investigator's First Name | MIMI |
| Investigator's Last Name | VAN DER LEDEN |
| Site Address: Street | 15201 SHADY GROVE DR |
| Site Address: City | ROCKVILLE |
| Site Address: State | |
| Site Address: Postal Code | 20850 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 9 |
| Date of submission (Pre-filled from custom function) | 29/JAN/2021 19:42 |
| **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 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (4)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:53**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| SAEID | USA-US215-2021-MRNA-1273-P301000001 |
| Serious | Yes ■ No ☐ |
| Death | Yes ■ No ☐ |
| Life threatening | Yes ☐ No ■ |
| Requires inpatient or prolongation of existing Hospitalization | Yes ■ No ☐ |
| Persistent or significant disability or incapacity | Yes ☐ No ■ |
| Congenital anomaly or birth defect | Yes ☐ No ■ |
| Other medically important event | Yes ☐ No ■ |
| Investigator's First Name | MIMI |
| Investigator's Last Name | VAN DER LEDEN |
| Site Address: Street | 15201 SHADY GROVE DR |
| Site Address: City | ROCKVILLE |
| Site Address: State | |
| Site Address: Postal Code | 20850 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 9 |
| Date of submission (Pre-filled from custom function) | 29/JAN/2021 19:54 |
| **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 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (5)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:53**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| SAEID | USA-US215-2021-MRNA-1273-P301000001 |
| Serious | Yes ■ No ☐ |
| Death | Yes ■ No ☐ |
| Life threatening | Yes ☐ No ■ |
| Requires inpatient or prolongation of existing Hospitalization | Yes ■ No ☐ |
| Persistent or significant disability or incapacity | Yes ☐ No ■ |
| Congenital anomaly or birth defect | Yes ☐ No ■ |
| Other medically important event | Yes ☐ No ■ |
| Investigator's First Name | MIMI |
| Investigator's Last Name | VAN DER LEDEN |
| Site Address: Street | 15201 SHADY GROVE DR |
| Site Address: City | ROCKVILLE |
| Site Address: State | |
| Site Address: Postal Code | 20850 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 9 |
| Date of submission (Pre-filled from custom function) | 09/FEB/2021 18:45 |
| **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 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (6)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:53**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| SAEID | USA-US215-2021-MRNA-1273-P301000001 |
| Serious | Yes ■ No ☐ |
| Death | Yes ■ No ☐ |
| Life threatening | Yes ☐ No ■ |
| Requires inpatient or prolongation of existing Hospitalization | Yes ■ No ☐ |
| Persistent or significant disability or incapacity | Yes ☐ No ■ |
| Congenital anomaly or birth defect | Yes ☐ No ■ |
| Other medically important event | Yes ☐ No ■ |
| Investigator's First Name | MIMI |
| Investigator's Last Name | VAN DER LEDEN |
| Site Address: Street | 15201 SHADY GROVE DR |
| Site Address: City | ROCKVILLE |
| Site Address: State | |
| Site Address: Postal Code | 20850 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 9 |
| Date of submission (Pre-filled from custom function) | 17/FEB/2021 11:42 |
| **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 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (7)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:53**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| SAEID | USA-US215-2021-MRNA-1273-P301000001 |
| Serious | Yes ■ No ☐ |
| Death | Yes ■ No ☐ |
| Life threatening | Yes ☐ No ■ |
| Requires inpatient or prolongation of existing Hospitalization | Yes ■ No ☐ |
| Persistent or significant disability or incapacity | Yes ☐ No ■ |
| Congenital anomaly or birth defect | Yes ☐ No ■ |
| Other medically important event | Yes ☐ No ■ |
| Investigator's First Name | MIMI |
| Investigator's Last Name | VAN DER LEDEN |
| Site Address: Street | 15201 SHADY GROVE DR |
| Site Address: City | ROCKVILLE |
| Site Address: State | |
| Site Address: Postal Code | 20850 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 9 |
| Date of submission (Pre-filled from custom function) | 05/APR/2021 12:16 |
| **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 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (8)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:53**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| SAEID | USA-US215-2021-MRNA-1273-P301000001 |
| Serious | Yes ■ No ☐ |
| Death | Yes ■ No ☐ |
| Life threatening | Yes ☐ No ■ |
| Requires inpatient or prolongation of existing Hospitalization | Yes ■ No ☐ |
| Persistent or significant disability or incapacity | Yes ☐ No ■ |
| Congenital anomaly or birth defect | Yes ☐ No ■ |
| Other medically important event | Yes ☐ No ■ |
| Investigator's First Name | MIMI |
| Investigator's Last Name | VAN DER LEDEN |
| Site Address: Street | 15201 SHADY GROVE DR |
| Site Address: City | ROCKVILLE |
| Site Address: State | |
| Site Address: Postal Code | 20850 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 9 |
| Date of submission (Pre-filled from custom function) | 09/APR/2021 10:58 |
| **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 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (9)**
**Data signed:** (b) (4) **16 Apr 2021 16:32:53**
**Generated On: 10 Jun 2021 10:28:25**

| | |
|---|---|
| SAEID | USA-US215-2021-MRNA-1273-P301000001 |
| Serious | Yes ■ No ☐ |
| Death | Yes ■ No ☐ |
| Life threatening | Yes ☐ No ■ |
| Requires inpatient or prolongation of existing Hospitalization | Yes ■ No ☐ |
| Persistent or significant disability or incapacity | Yes ☐ No ■ |
| Congenital anomaly or birth defect | Yes ☐ No ■ |
| Other medically important event | Yes ☐ No ■ |
| Investigator's First Name | MIMI |
| Investigator's Last Name | VAN DER LEDEN |
| Site Address: Street | 15201 SHADY GROVE DR |
| Site Address: City | ROCKVILLE |
| Site Address: State | |
| Site Address: Postal Code | 20850 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 9 |
| Date of submission (Pre-filled from custom function) | 12/APR/2021 15:08 |
| **Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.** | True |

Audit

US3952094 (Prod: Synexus - Optimal Research - Rockville)

**US3952094**
**Form: Participant Creation**
**Generated On: 10 Jun 2021 10:28:25**
Participant ID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:48:08 |
| User entered 'US3952094' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 15 Sep 2020 16:04:26 |



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**US3952094**
**Form: Participant Creation**
**Generated On: 10 Jun 2021 10:28:25**

mRNA-1273-P301 Completion Guidelines

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3796283

**US3952094**
**Folder: Screening**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**
Was this visit performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User closed query 'Per CDM: Please complete all forms for this visit. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 29 Sep 2020 15:00:21 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:19:17 |
| Query 'Per CDM: Please complete all forms for this visit. Thank you.' answered with 'updatd' (Site from DM). | Nick Bart (b) (4) | 28 Sep 2020 15:19:13 |
| User opened query 'Per CDM: Please complete all forms for this visit. Thank you.' (Site from DM). | (b) (4), (b) (6) | 24 Sep 2020 12:48:50 |

**US3952094**
**Folder: Screening**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**
Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '15 SEP 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 15 Sep 2020 16:04:27 |

**US3952094**
**Folder: Screening**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**
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 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Clinic (Clinic)' | Nick Bart (b) (4) | 28 Sep 2020 15:19:17 |

**US3952094**
**Folder: Screening**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**
Folder OID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'SCRN' | System | 28 Sep 2020 15:19:17 |

**US3952094**
**Folder: Screening**
**Form: Demographics**
**Generated On: 10 Jun 2021 10:28:25**
Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered (b) (6) 1963' | RWS_ENDPOINT ENDPOINT (b) (4) | 15 Sep 2020 16:04:28 |



FDA-CBER-2022-1614-3796288

**US3952094**
**Folder: Screening**
**Form: Demographics**
**Generated On: 10 Jun 2021 10:28:25**
Age

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '57' | Nick Bart (b) (4) | 17 Sep 2020 20:51:03 |

**US3952094**
**Folder: Screening**
**Form: Demographics**
**Generated On: 10 Jun 2021 10:28:25**
Age Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'YEARS' | System | 17 Sep 2020 20:51:03 |

**US3952094**
**Folder: Screening**
**Form: Demographics**
**Generated On: 10 Jun 2021 10:28:25**
Age (Derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '57' | System | 15 Sep 2020 19:15:27 |

**US3952094**
**Folder: Screening**
**Form: Demographics**
**Generated On: 10 Jun 2021 10:28:25**
Sex

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Male (M)' | Nick Bart (b) (4) | 17 Sep 2020 20:51:03 |

**US3952094**
**Folder: Screening**
**Form: Demographics**
**Generated On: 10 Jun 2021 10:28:25**
Ethnicity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Hispanic or Latino (HISPANIC OR LATINO)' | Nick Bart (b) (4) | 17 Sep 2020 20:51:03 |

**US3952094**
**Folder: Screening**
**Form: Demographics**
**Generated On: 10 Jun 2021 10:28:25**
White

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '1' | Nick Bart (b) (4) | 17 Sep 2020 20:51:03 |



FDA-CBER-2022-1614-3796294

**US3952094**
**Folder: Screening**
**Form: Demographics**
**Generated On: 10 Jun 2021 10:28:25**
Black

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 17 Sep 2020 20:51:03 |

**US3952094**
**Folder: Screening**
**Form: Demographics**
**Generated On: 10 Jun 2021 10:28:25**
Asian

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 17 Sep 2020 20:51:03 |

**US3952094**
**Folder: Screening**
**Form: Demographics**
**Generated On: 10 Jun 2021 10:28:25**
American Indian or Alaska Native

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) (b) (4) | 17 Sep 2020 20:51:03 |

**US3952094**
**Folder: Screening**
**Form: Demographics**
**Generated On: 10 Jun 2021 10:28:25**
Native Hawaiian or other Pacific Islander

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 17 Sep 2020 20:51:03 |

**US3952094**
**Folder: Screening**
**Form: Demographics**
**Generated On: 10 Jun 2021 10:28:25**
Other

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 17 Sep 2020 20:51:03 |



FDA-CBER-2022-1614-3796299

**US3952094**
**Folder: Screening**
**Form: Demographics**
**Generated On: 10 Jun 2021 10:28:25**
If race is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 17 Sep 2020 20:51:03 |

**US3952094**
**Folder: Screening**
**Form: Demographics**
**Generated On: 10 Jun 2021 10:28:25**
Unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) (b) (4) | 17 Sep 2020 20:51:03 |

**US3952094**
**Folder: Screening**
**Form: Demographics**
**Generated On: 10 Jun 2021 10:28:25**
Not reported

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 17 Sep 2020 20:51:03 |



FDA-CBER-2022-1614-3796302

**US3952094**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 10 Jun 2021 10:28:25**
Date of Informed Consent *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '15 Sep 2020' | Stephanie Melton (b) (4) (b) (4) | 15 Sep 2020 19:15:27 |

**US3952094**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 10 Jun 2021 10:28:25**
Month and Year of Informed Consent (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'Sep 2020' | System | 15 Sep 2020 19:15:27 |

**US3952094**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 10 Jun 2021 10:28:25**
Year of Informed Consent (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '2020' | System | 15 Sep 2020 19:15:27 |



FDA-CBER-2022-1614-3796305

**US3952094**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 10 Jun 2021 10:28:25**
Protocol Version

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Amendment 3 (3)' | Stephanie Melton (b) (4) (b) (4) | 15 Sep 2020 19:15:27 |

**US3952094**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 10 Jun 2021 10:28:25**
Was participant enrolled in the study?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Stephanie Melton (b) (4) (b) (4) | 15 Sep 2020 19:15:27 |

**US3952094**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 10 Jun 2021 10:28:25**
If No, indicate reason for screen fail

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Stephanie Melton (b) (4) (b) (4) | 15 Sep 2020 19:15:27 |

**US3952094**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 10 Jun 2021 10:28:25**
If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Stephanie Melton (b) (4) (b) (4) | 15 Sep 2020 19:15:27 |

**US3952094**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 10 Jun 2021 10:28:25**
Was this participant screened previously?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Stephanie Melton (b) (4) (b) (4) | 15 Sep 2020 19:15:27 |

**US3952094**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 10 Jun 2021 10:28:25**
If Yes, previous participant number

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) | 15 Sep 2020 16:04:27 |

**US3952094**
**Folder: Screening**
**Form: Enrollment**
**Generated On: 10 Jun 2021 10:28:25**
Enrollment Trigger

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 15 Sep 2020 19:15:31 |

**US3952094**
**Folder: Screening**
**Form: Inclusion/Exclusion Criteria Summary**
**Generated On: 10 Jun 2021 10:28:25**
Did the participant meet all eligibility criteria?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Stephanie Melton (b) (4) (b) (4) | 15 Sep 2020 19:15:31 |

**US3952094**
**Folder: Screening**
**Form: Medical History Summary**
**Generated On: 10 Jun 2021 10:28:25**
Were any significant conditions reported?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:24:39 |

**US3952094**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 10 Jun 2021 10:28:25**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| 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) (b) (4) | 28 Sep 2020 15:26:45 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 15:26:45 |
| Data point term sent to Coder | System | 28 Sep 2020 15:25:31 |
| User entered 'hypertension' | Nick Bart (b) (4) | 28 Sep 2020 15:25:01 |

**US3952094**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 10 Jun 2021 10:28:25**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'un UNK 2010' | Nick Bart (b) (4) | 28 Sep 2020 15:25:01 |

**US3952094**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:25:01 |

**US3952094**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 10 Jun 2021 10:28:25**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:25:01 |

**US3952094**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 10 Jun 2021 10:28:25**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:25:01 |

**US3952094**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 10 Jun 2021 10:28:25**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:25:01 |

**US3952094**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 10 Jun 2021 10:28:25**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'Jan 2010' | System | 28 Sep 2020 15:25:01 |

**US3952094**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 10 Jun 2021 10:28:25**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '2010' | System | 28 Sep 2020 15:25:01 |



FDA-CBER-2022-1614-3796322

**US3952094**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 10 Jun 2021 10:28:25**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 28 Sep 2020 15:25:01 |

**US3952094**
**Folder: Screening**
**Form: Medical History (1)**
**Generated On: 10 Jun 2021 10:28:25**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 28 Sep 2020 15:25:01 |



FDA-CBER-2022-1614-3796324

**US3952094**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 10 Jun 2021 10:28:25**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 15:26:49 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 15:26:49 |
| Data point term sent to Coder | System | 28 Sep 2020 15:25:30 |
| User entered 'high cholesterol' | Nick Bart (b) (4) | 28 Sep 2020 15:25:11 |

**US3952094**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 10 Jun 2021 10:28:25**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'un UNK 2010' | Nick Bart (b) (4) | 28 Sep 2020 15:25:11 |

**US3952094**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:25:11 |

**US3952094**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 10 Jun 2021 10:28:25**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:25:11 |

**US3952094**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 10 Jun 2021 10:28:25**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:25:11 |

**US3952094**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 10 Jun 2021 10:28:25**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:25:11 |

**US3952094**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 10 Jun 2021 10:28:25**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'Jan 2010' | System | 28 Sep 2020 15:25:11 |

**US3952094**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 10 Jun 2021 10:28:25**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '2010' | System | 28 Sep 2020 15:25:11 |



FDA-CBER-2022-1614-3796332

**US3952094**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 10 Jun 2021 10:28:25**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 28 Sep 2020 15:25:11 |

**US3952094**
**Folder: Screening**
**Form: Medical History (2)**
**Generated On: 10 Jun 2021 10:28:25**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 28 Sep 2020 15:25:11 |



FDA-CBER-2022-1614-3796334

**US3952094**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 10 Jun 2021 10:28:25**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 15:26:45 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 15:26:45 |
| Data point term sent to Coder | System | 28 Sep 2020 15:25:30 |
| User entered 'diabetes' | Nick Bart (b) (4) | 28 Sep 2020 15:25:23 |

**US3952094**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 10 Jun 2021 10:28:25**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'un UNK 2000' | Nick Bart (b) (4) | 28 Sep 2020 15:25:23 |

**US3952094**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:25:23 |

**US3952094**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 10 Jun 2021 10:28:25**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:25:23 |

**US3952094**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 10 Jun 2021 10:28:25**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:25:23 |

**US3952094**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 10 Jun 2021 10:28:25**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:25:23 |

**US3952094**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 10 Jun 2021 10:28:25**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'Jan 2000' | System | 28 Sep 2020 15:25:23 |

**US3952094**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 10 Jun 2021 10:28:25**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '2000' | System | 28 Sep 2020 15:25:23 |



FDA-CBER-2022-1614-3796342

**US3952094**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 10 Jun 2021 10:28:25**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 28 Sep 2020 15:25:23 |

**US3952094**
**Folder: Screening**
**Form: Medical History (3)**
**Generated On: 10 Jun 2021 10:28:25**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 28 Sep 2020 15:25:23 |



FDA-CBER-2022-1614-3796344

**US3952094**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 10 Jun 2021 10:28:25**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Cervical disc herniation - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Nov 2020 17:52:28 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Nov 2020 17:52:28 |
| Data point term sent to Coder | System | 28 Sep 2020 15:26:34 |
| User entered 'neck hernia' | Nick Bart (b) (4) | 28 Sep 2020 15:25:36 |

**US3952094**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 10 Jun 2021 10:28:25**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'un UNK 2008' | Nick Bart (b) (4) | 28 Sep 2020 15:25:36 |

**US3952094**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:25:36 |

**US3952094**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 10 Jun 2021 10:28:25**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:25:36 |



FDA-CBER-2022-1614-3796348

**US3952094**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 10 Jun 2021 10:28:25**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:25:36 |

**US3952094**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 10 Jun 2021 10:28:25**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:25:36 |

**US3952094**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 10 Jun 2021 10:28:25**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'Jan 2008' | System | 28 Sep 2020 15:25:36 |

**US3952094**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 10 Jun 2021 10:28:25**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '2008' | System | 28 Sep 2020 15:25:36 |

**US3952094**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 10 Jun 2021 10:28:25**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 28 Sep 2020 15:25:36 |

**US3952094**
**Folder: Screening**
**Form: Medical History (4)**
**Generated On: 10 Jun 2021 10:28:25**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 28 Sep 2020 15:25:36 |



FDA-CBER-2022-1614-3796354

**US3952094**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 10 Jun 2021 10:28:25**
Condition

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 15:27:36 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 15:27:36 |
| Data point term sent to Coder | System | 28 Sep 2020 15:26:36 |
| User entered 'left knee pain' | Nick Bart (b) (4) | 28 Sep 2020 15:25:48 |

**US3952094**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 10 Jun 2021 10:28:25**
Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '27 Feb 2020' | Nick Bart (b) (4) | 28 Sep 2020 15:25:48 |



FDA-CBER-2022-1614-3796356

**US3952094**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:25:48 |



FDA-CBER-2022-1614-3796357

**US3952094**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 10 Jun 2021 10:28:25**
Condition ongoing at study entry

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:25:48 |

**US3952094**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 10 Jun 2021 10:28:25**
If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:25:48 |

**US3952094**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 10 Jun 2021 10:28:25**
Stop date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:25:48 |

**US3952094**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 10 Jun 2021 10:28:25**
Start Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'Feb 2020' | System | 28 Sep 2020 15:25:48 |

**US3952094**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 10 Jun 2021 10:28:25**
Start Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '2020' | System | 28 Sep 2020 15:25:48 |



FDA-CBER-2022-1614-3796362

**US3952094**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 10 Jun 2021 10:28:25**
Stop Month and Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 28 Sep 2020 15:25:48 |

**US3952094**
**Folder: Screening**
**Form: Medical History (5)**
**Generated On: 10 Jun 2021 10:28:25**
Stop Year (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 28 Sep 2020 15:25:48 |



FDA-CBER-2022-1614-3796364

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Were vital signs assessed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:23:28 |

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Date of assessment *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '15 Sep 2020' | Nick Bart (b) (4) | 28 Sep 2020 15:23:28 |

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Time of assessment *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '12:03' | Nick Bart (b) (4) | 28 Sep 2020 15:23:28 |

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Vital Signs Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '15 Sep 2020 12:03' | System | 28 Sep 2020 15:23:28 |

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Height *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered '60.0' in | Nick Bart (b) (4) | 28 Sep 2020 15:23:28 |
| DataPoint set to visible. | System | 15 Sep 2020 19:15:31 |

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Weight *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered '140.0' lb | Nick Bart (b) (4) | 28 Sep 2020 15:23:28 |
| DataPoint set to visible. | System | 15 Sep 2020 19:15:31 |

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
BMI *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '27.39904' | System | 28 Sep 2020 15:23:28 |
| DataPoint set to visible. | System | 15 Sep 2020 19:15:31 |

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
BMI units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'kg/m2' | System | 28 Sep 2020 15:23:28 |
| DataPoint set to visible. | System | 15 Sep 2020 19:15:31 |

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Temperature *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 28 Sep 2020 15:23:43 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 28 Sep 2020 15:23:43 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Nick Bart (b) (4) | 28 Sep 2020 15:23:43 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 28 Sep 2020 15:23:28 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:23:28 |

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Route of measurement

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:23:28 |



FDA-CBER-2022-1614-3796374

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
If Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:23:28 |

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Pulse *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 28 Sep 2020 15:23:43 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 28 Sep 2020 15:23:43 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Nick Bart (b) (4) | 28 Sep 2020 15:23:43 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 28 Sep 2020 15:23:28 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:23:28 |



FDA-CBER-2022-1614-3796376

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Pulse units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'bpm' | System | 28 Sep 2020 15:23:43 |
| User entered empty. | System | 28 Sep 2020 15:23:28 |

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Respiratory Rate *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 28 Sep 2020 15:23:43 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 28 Sep 2020 15:23:43 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Nick Bart (b) (4) | 28 Sep 2020 15:23:43 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 28 Sep 2020 15:23:28 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:23:28 |

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Respiratory Rate units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'breaths/min' | System | 28 Sep 2020 15:23:43 |
| User entered empty. | System | 28 Sep 2020 15:23:28 |

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Systolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 28 Sep 2020 15:23:43 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 28 Sep 2020 15:23:43 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Nick Bart (b) (4) | 28 Sep 2020 15:23:43 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 28 Sep 2020 15:23:28 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:23:28 |

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Systolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'mmHg' | System | 28 Sep 2020 15:23:43 |
| User entered empty. | System | 28 Sep 2020 15:23:28 |

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Diastolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 28 Sep 2020 15:23:47 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Nick Bart (b) (4) | 28 Sep 2020 15:23:47 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 28 Sep 2020 15:23:43 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 28 Sep 2020 15:23:43 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 28 Sep 2020 15:23:43 |
| User entered 'ND" (non-conformant). | Nick Bart (b) (4) | 28 Sep 2020 15:23:43 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 28 Sep 2020 15:23:28 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:23:28 |

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'mmHg' | System | 28 Sep 2020 15:23:47 |
| User entered empty. | System | 28 Sep 2020 15:23:28 |

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Height (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3796384

**US3952094**
**Folder: Screening**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Weight (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3796385

**US3952094**
**Folder: Screening**
**Form: Physical Examination**
**Generated On: 10 Jun 2021 10:28:25**
Was the physical examination performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:19:38 |

**US3952094**
**Folder: Screening**
**Form: Physical Examination**
**Generated On: 10 Jun 2021 10:28:25**
Date of examination *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '15 Sep 2020' | Nick Bart (b) (4) | 28 Sep 2020 15:19:38 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Retail or Restaurant Operations,** particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Warehouse shipping and fulfillment centers** and jobs (e.g., Amazon facilities)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Other**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Specify**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'walks 5 miles daily (monday through friday). groceries once weekly.' | Nick Bart (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**No Risk Identified**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:20:52 |



FDA-CBER-2022-1614-3796401

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Resides in Nursing Home or Assisted Living Facility**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Resides in a single family home** (i.e., detached housing)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Other**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '1' | Nick Bart (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Screening**
**Form: Risk of Exposure**
**Generated On: 10 Jun 2021 10:28:25**
**Specify**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'rents a room with one roommate' | Nick Bart (b) (4) | 28 Sep 2020 15:20:52 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**
Was this visit performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:26:00 |



FDA-CBER-2022-1614-3796409

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**
Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '15 Sep 2020' | Nick Bart (b) (4) | 28 Sep 2020 15:26:00 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**
Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Clinic (Clinic)' | Nick Bart (b) (4) | 28 Sep 2020 15:26:00 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**
Folder OID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered 'VISIT1' | System | 28 Sep 2020 15:26:00 |



FDA-CBER-2022-1614-3796412

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 10 Jun 2021 10:28:25**
What was the date of randomization? *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '15 SEP 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 15 Sep 2020 17:29:43 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 10 Jun 2021 10:28:25**
What was the participant's randomization number?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '145978' | RWS_ENDPOINT ENDPOINT (b) (4) | 15 Sep 2020 17:29:43 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 10 Jun 2021 10:28:25**
In what Cohort was the participant enrolled?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '>=18 and <65 years and at risk (2)' | RWS_ENDPOINT ENDPOINT (b) (4) | 15 Sep 2020 17:29:43 |



FDA-CBER-2022-1614-3796415

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 10 Jun 2021 10:28:25**
Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:26:23 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 10 Jun 2021 10:28:25**
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) (b) (4) | 28 Sep 2020 15:26:23 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 10 Jun 2021 10:28:25**
Severe obesity (body mass index > or = 40kg/m2

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:26:23 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 10 Jun 2021 10:28:25**
Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:26:23 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 10 Jun 2021 10:28:25**
Liver Disease

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:26:23 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Randomization**
**Generated On: 10 Jun 2021 10:28:25**
Human Immunodeficiency Virus (HIV) infection

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:26:23 |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 09:15:43 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 09:15:42 |



FDA-CBER-2022-1614-3796421

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing**
**Generated On: 10 Jun 2021 10:28:25**
Height

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered missing code ND - Not Done. | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796422

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing**
**Generated On: 10 Jun 2021 10:28:25**
Weight

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered missing code ND - Not Done. | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing**
**Generated On: 10 Jun 2021 10:28:25**
Height

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered missing code ND - Not Done. | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796424

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing**
**Generated On: 10 Jun 2021 10:28:25**
Weight

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered missing code ND - Not Done. | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796425

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Timepoint

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796426

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Were vital signs assessed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Date of assessment *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '15 Sep 2020' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796428

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Time of assessment *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '12:03' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796429

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Vital Signs Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered '15 Sep 2020 12:03' | System | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796430

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '36.8' C | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796431

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Route of measurement

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Oral (Oral)' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
If Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Pulse *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '68' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796434

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Pulse units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered 'bpm' | System | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796435

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Respiratory Rate *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '14' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796436

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Respiratory Rate units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered 'breaths/min' | System | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796437

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Systolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User closed query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM). | (b) (4), (b) (6) | 10 Nov 2020 13:22:09 |
| Query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'NCS' (Site from DM). | Nick Bart (b) (4) | 03 Nov 2020 19:09:32 |
| User opened query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM). | (b) (4), (b) (6) | 26 Oct 2020 03:08:35 |
| User entered '144' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Systolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered 'mmHg' | System | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796439

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Diastolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '83' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796440

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered 'mmHg' | System | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796441

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing**
**Generated On: 10 Jun 2021 10:28:25**
Height

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered missing code ND - Not Done. | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796442

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing**
**Generated On: 10 Jun 2021 10:28:25**
Weight

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered missing code ND - Not Done. | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Timepoint

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796444

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Were vital signs assessed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796445

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Date of assessment *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '15 Sep 2020' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Time of assessment *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '15:20' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Vital Signs Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered '15 Sep 2020 15:20' | System | 28 Sep 2020 15:28:55 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '36.5' C | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Route of measurement

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Oral (Oral)' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
If Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796451

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Pulse *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '57' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796452

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Pulse units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered 'bpm' | System | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796453

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Respiratory Rate *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '12' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796454

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Respiratory Rate units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered 'breaths/min' | System | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796455

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Systolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User closed query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM). | (b) (4), (b) (6) | 10 Nov 2020 13:22:17 |
| Query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'NCS' (Site from DM). | Nick Bart (b) (4) | 03 Nov 2020 19:09:48 |
| User opened query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM). | (b) (4), (b) (6) | 26 Oct 2020 03:08:50 |
| User entered '145' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Systolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered 'mmHg' | System | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796457

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Diastolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '72' | Nick Bart (b) (4) | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796458

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered 'mmHg' | System | 28 Sep 2020 15:28:55 |



FDA-CBER-2022-1614-3796459

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Physical Examination**
**Generated On: 10 Jun 2021 10:28:25**
Was the physical examination performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:26:07 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Physical Examination**
**Generated On: 10 Jun 2021 10:28:25**
Date of examination *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:26:07 |



FDA-CBER-2022-1614-3796461

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
Was study treatment given?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User closed query 'Per CDM: Please complete remaining forms for this visit. Thank you.' (Site from DM). | (b) (4), (b) (6) | 09 Nov 2020 11:09:44 |
| Query 'Per CDM: Please complete remaining forms for this visit. Thank you.' answered with 'already completed' (Site from DM). | Nick Bart (b) (4) | 03 Nov 2020 19:10:12 |
| User opened query 'Per CDM: Please complete remaining forms for this visit. Thank you.' (Site from DM). | (b) (4), (b) (6) | 24 Sep 2020 12:49:16 |
| User entered 'Yes (Y)' | Stephanie Melton (b) (4) (b) (4) | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
If No, reason not given

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Stephanie Melton (b) (4) (b) (4) | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Stephanie Melton (b) (4) (b) (4) | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
What was the study treatment?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
What was the treatment date? *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '15 Sep 2020' | Stephanie Melton (b) (4) (b) (4) | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
What was the treatment time? *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '13:52' | Stephanie Melton (b) (4) (b) (4) | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
Treatment Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered '15 Sep 2020 13:52' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796468

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
Which arm was used to give treatment?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Left Arm (LEFT ARM)' | Stephanie Melton (b) (4) (b) (4) | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered 'ONCE' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796470

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered 'INTRAMUSCULAR' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Immunogenicity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Was the sample collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:26:38 |



FDA-CBER-2022-1614-3796472

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Immunogenicity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Collection date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '15 Sep 2020' | Nick Bart (b) (4) | 28 Sep 2020 15:26:38 |



FDA-CBER-2022-1614-3796473

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Immunogenicity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Collection time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '12:41' | Nick Bart (b) (4) | 28 Sep 2020 15:26:38 |



FDA-CBER-2022-1614-3796474

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Immunogenicity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Collection date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered '15 Sep 2020 12:41' | System | 28 Sep 2020 15:26:38 |



FDA-CBER-2022-1614-3796475

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab**
**Generated On: 10 Jun 2021 10:28:25**
Collection date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '15 Sep 2020' | Nick Bart (b) (4) | 28 Sep 2020 15:27:15 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab (1)**
**Generated On: 10 Jun 2021 10:28:25**
Lab Test

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Nick Bart (b) (4) | 28 Sep 2020 15:27:15 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab (1)**
**Generated On: 10 Jun 2021 10:28:25**
Was the sample collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:27:15 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab (1)**
**Generated On: 10 Jun 2021 10:28:25**
Collection time *(00:00 - 23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '12:44' | Nick Bart (b) (4) | 28 Sep 2020 15:27:15 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab (1)**
**Generated On: 10 Jun 2021 10:28:25**
Collection date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered '15 Sep 2020 12:44' | System | 28 Sep 2020 15:27:15 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab (2)**
**Generated On: 10 Jun 2021 10:28:25**
Lab Test

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Nick Bart (b) (4) | 28 Sep 2020 15:27:15 |



FDA-CBER-2022-1614-3796481

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab (2)**
**Generated On: 10 Jun 2021 10:28:25**
Was the sample collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:27:15 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab (2)**
**Generated On: 10 Jun 2021 10:28:25**
Collection time *(00:00 - 23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:27:15 |



FDA-CBER-2022-1614-3796483

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Central Laboratory - Nasopharyngeal Swab (2)**
**Generated On: 10 Jun 2021 10:28:25**
Collection date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered empty. | System | 28 Sep 2020 15:27:15 |



FDA-CBER-2022-1614-3796484

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:26:03 |

**US3952094**
**Folder: Visit 1 Day 1**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered '1' | System | 28 Sep 2020 15:26:03 |



FDA-CBER-2022-1614-3796486

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T15:26:24', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'fadf0009-0041-4a92-b319-2f724d795c8c' | System | 15 Sep 2020 19:26:57 |
| User entered 'Yes (Y)' | System | 15 Sep 2020 19:26:57 |



FDA-CBER-2022-1614-3796488

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T15:26:36', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'fadf0009-0041-4a92-b319-2f724d795c8c' | System | 15 Sep 2020 19:26:57 |
| User entered '97.1' | System | 15 Sep 2020 19:26:57 |



FDA-CBER-2022-1614-3796489

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T15:26:43', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'fadf0009-0041-4a92-b319-2f724d795c8c' | System | 15 Sep 2020 19:26:57 |
| User entered 'No (N)' | System | 15 Sep 2020 19:26:57 |



FDA-CBER-2022-1614-3796490

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T15:26:50', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'fadf0009-0041-4a92-b319-2f724d795c8c' | System | 15 Sep 2020 19:26:57 |
| User entered '15 Sep 2020 15:26' | System | 15 Sep 2020 19:26:57 |



FDA-CBER-2022-1614-3796491

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '15 Sep 2020 14:12' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796492

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '15 Sep 2020 16:42' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 1, after vaccination (at home)' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T22:03:02', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'f3b9ff6f-e16a-4708-96c7-fde1120e4103' | System | 16 Sep 2020 02:03:53 |
| User entered 'Yes (Y)' | System | 16 Sep 2020 02:03:53 |



FDA-CBER-2022-1614-3796495

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T22:03:26', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'f3b9ff6f-e16a-4708-96c7-fde1120e4103' | System | 16 Sep 2020 02:03:53 |
| User entered '97.3' | System | 16 Sep 2020 02:03:53 |



FDA-CBER-2022-1614-3796496

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T22:03:36', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'f3b9ff6f-e16a-4708-96c7-fde1120e4103' | System | 16 Sep 2020 02:03:53 |
| User entered 'No (N)' | System | 16 Sep 2020 02:03:53 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T22:03:47', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'f3b9ff6f-e16a-4708-96c7-fde1120e4103' | System | 16 Sep 2020 02:03:53 |
| User entered '15 Sep 2020 22:03' | System | 16 Sep 2020 02:03:53 |



FDA-CBER-2022-1614-3796498

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '15 Sep 2020 17:37' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796499

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '16 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796500

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 2' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-16T21:45:57', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '69494908-caa9-4a54-be45-1a5dc7612b0c' | System | 17 Sep 2020 01:46:52 |
| User entered 'Yes (Y)' | System | 17 Sep 2020 01:46:52 |



FDA-CBER-2022-1614-3796502

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-16T21:46:24', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '69494908-caa9-4a54-be45-1a5dc7612b0c' | System | 17 Sep 2020 01:46:52 |
| User entered '97.3' | System | 17 Sep 2020 01:46:52 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-16T21:46:33', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '69494908-caa9-4a54-be45-1a5dc7612b0c' | System | 17 Sep 2020 01:46:52 |
| User entered 'No (N)' | System | 17 Sep 2020 01:46:52 |



FDA-CBER-2022-1614-3796504

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-16T21:46:44', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '69494908-caa9-4a54-be45-1a5dc7612b0c' | System | 17 Sep 2020 01:46:52 |
| User entered '16 Sep 2020 21:46' | System | 17 Sep 2020 01:46:52 |



FDA-CBER-2022-1614-3796505

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '16 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796506

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '17 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796507

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 3' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796508

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T11:03:27', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '3542bebe-2726-45e1-b761-acd951d07180' | System | 18 Sep 2020 15:04:04 |
| User entered 'Yes (Y)' | System | 18 Sep 2020 15:04:04 |



FDA-CBER-2022-1614-3796509

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T11:03:43', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '3542bebe-2726-45e1-b761-acd951d07180' | System | 18 Sep 2020 15:04:04 |
| User entered '96.3' | System | 18 Sep 2020 15:04:04 |



FDA-CBER-2022-1614-3796510

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T11:03:53', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '3542bebe-2726-45e1-b761-acd951d07180' | System | 18 Sep 2020 15:04:04 |
| User entered 'No (N)' | System | 18 Sep 2020 15:04:04 |



FDA-CBER-2022-1614-3796511

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T11:03:58', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '3542bebe-2726-45e1-b761-acd951d07180' | System | 18 Sep 2020 15:04:04 |
| User entered '18 Sep 2020 11:03' | System | 18 Sep 2020 15:04:04 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '17 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796513

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '18 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796514

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 4' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T21:28:00', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '6b3fbc1b-937b-477c-9515-8aebd43aa5de' | System | 19 Sep 2020 01:28:39 |
| User entered 'Yes (Y)' | System | 19 Sep 2020 01:28:39 |



FDA-CBER-2022-1614-3796516

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T21:28:18', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '6b3fbc1b-937b-477c-9515-8aebd43aa5de' | System | 19 Sep 2020 01:28:39 |
| User entered '98.1' | System | 19 Sep 2020 01:28:39 |



FDA-CBER-2022-1614-3796517

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T21:28:27', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '6b3fbc1b-937b-477c-9515-8aebd43aa5de' | System | 19 Sep 2020 01:28:39 |
| User entered 'No (N)' | System | 19 Sep 2020 01:28:39 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T21:28:33', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '6b3fbc1b-937b-477c-9515-8aebd43aa5de' | System | 19 Sep 2020 01:28:39 |
| User entered '18 Sep 2020 21:28' | System | 19 Sep 2020 01:28:39 |



FDA-CBER-2022-1614-3796519

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '18 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796520

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '19 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796521

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 5' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796522

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-19T23:16:32', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '35946e6e-98c2-4237-b9f6-fab92e598dc4' | System | 20 Sep 2020 03:16:59 |
| User entered 'Yes (Y)' | System | 20 Sep 2020 03:16:59 |



FDA-CBER-2022-1614-3796523

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-19T23:16:42', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '35946e6e-98c2-4237-b9f6-fab92e598dc4' | System | 20 Sep 2020 03:16:59 |
| User entered '95.7' | System | 20 Sep 2020 03:16:59 |



FDA-CBER-2022-1614-3796524

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-19T23:16:48', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '35946e6e-98c2-4237-b9f6-fab92e598dc4' | System | 20 Sep 2020 03:16:59 |
| User entered 'No (N)' | System | 20 Sep 2020 03:16:59 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-19T23:16:54', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '35946e6e-98c2-4237-b9f6-fab92e598dc4' | System | 20 Sep 2020 03:16:59 |
| User entered '19 Sep 2020 23:16' | System | 20 Sep 2020 03:16:59 |



FDA-CBER-2022-1614-3796526

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '19 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796527

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '20 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796528

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 6' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796529

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-20T22:04:15', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c7d3b429-ffac-409c-944e-beb0154fd2c3' | System | 21 Sep 2020 02:04:47 |
| User entered 'Yes (Y)' | System | 21 Sep 2020 02:04:47 |



FDA-CBER-2022-1614-3796530

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-20T22:04:26', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c7d3b429-ffac-409c-944e-beb0154fd2c3' | System | 21 Sep 2020 02:04:47 |
| User entered '95.7' | System | 21 Sep 2020 02:04:47 |



FDA-CBER-2022-1614-3796531

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-20T22:04:39', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c7d3b429-ffac-409c-944e-beb0154fd2c3' | System | 21 Sep 2020 02:04:47 |
| User entered 'No (N)' | System | 21 Sep 2020 02:04:47 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-20T22:04:43', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c7d3b429-ffac-409c-944e-beb0154fd2c3' | System | 21 Sep 2020 02:04:47 |
| User entered '20 Sep 2020 22:04' | System | 21 Sep 2020 02:04:47 |



FDA-CBER-2022-1614-3796533

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '20 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796534

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '21 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796535

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 7' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-21T22:00:08', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '9f4039e1-06cf-41bc-9616-64253b1134f7' | System | 22 Sep 2020 02:00:42 |
| User entered 'Yes (Y)' | System | 22 Sep 2020 02:00:42 |



FDA-CBER-2022-1614-3796537

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-21T22:00:25', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '9f4039e1-06cf-41bc-9616-64253b1134f7' | System | 22 Sep 2020 02:00:42 |
| User entered '96.8' | System | 22 Sep 2020 02:00:42 |



FDA-CBER-2022-1614-3796538

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-21T22:00:32', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '9f4039e1-06cf-41bc-9616-64253b1134f7' | System | 22 Sep 2020 02:00:42 |
| User entered 'No (N)' | System | 22 Sep 2020 02:00:42 |



FDA-CBER-2022-1614-3796539

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-21T22:00:35', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '9f4039e1-06cf-41bc-9616-64253b1134f7' | System | 22 Sep 2020 02:00:42 |
| User entered '21 Sep 2020 22:00' | System | 22 Sep 2020 02:00:42 |



FDA-CBER-2022-1614-3796540

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '21 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796541

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Temperature_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '22 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796542

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T15:27:00', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '82c6d707-c3fd-4c2d-b3cf-a06dbaf42494' | System | 15 Sep 2020 19:27:26 |
| User entered 'None (1)' | System | 15 Sep 2020 19:27:26 |



FDA-CBER-2022-1614-3796544

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T15:27:07', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '82c6d707-c3fd-4c2d-b3cf-a06dbaf42494' | System | 15 Sep 2020 19:27:26 |
| User entered 'No (N)' | System | 15 Sep 2020 19:27:26 |



FDA-CBER-2022-1614-3796545

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T15:27:12', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '82c6d707-c3fd-4c2d-b3cf-a06dbaf42494' | System | 15 Sep 2020 19:27:26 |
| User entered 'No (N)' | System | 15 Sep 2020 19:27:26 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T15:27:17', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '82c6d707-c3fd-4c2d-b3cf-a06dbaf42494' | System | 15 Sep 2020 19:27:26 |
| User entered 'None (1)' | System | 15 Sep 2020 19:27:26 |



FDA-CBER-2022-1614-3796547

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T15:27:21', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '82c6d707-c3fd-4c2d-b3cf-a06dbaf42494' | System | 15 Sep 2020 19:27:26 |
| User entered '15 Sep 2020 15:27' | System | 15 Sep 2020 19:27:26 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '15 Sep 2020 14:12' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796549

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '15 Sep 2020 16:42' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796550

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 1, after vaccination (at home)' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |



FDA-CBER-2022-1614-3796552

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |



FDA-CBER-2022-1614-3796554

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |



FDA-CBER-2022-1614-3796555

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

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

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |



FDA-CBER-2022-1614-3796556

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |



FDA-CBER-2022-1614-3796557

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |



FDA-CBER-2022-1614-3796558

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '15 Sep 2020 17:37' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796559

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '16 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796560

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 2' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796561

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-16T21:48:17', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1034dc48-ba76-47f3-a739-985b3eade6f1' | System | 17 Sep 2020 01:49:06 |
| User entered 'None (1)' | System | 17 Sep 2020 01:49:06 |



FDA-CBER-2022-1614-3796562

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-16T21:48:23', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1034dc48-ba76-47f3-a739-985b3eade6f1' | System | 17 Sep 2020 01:49:06 |
| User entered 'No (N)' | System | 17 Sep 2020 01:49:06 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-16T21:48:31', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1034dc48-ba76-47f3-a739-985b3eade6f1' | System | 17 Sep 2020 01:49:06 |
| User entered 'No (N)' | System | 17 Sep 2020 01:49:06 |



FDA-CBER-2022-1614-3796564

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-16T21:48:53', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1034dc48-ba76-47f3-a739-985b3eade6f1' | System | 17 Sep 2020 01:49:06 |
| User entered 'None (1)' | System | 17 Sep 2020 01:49:06 |



FDA-CBER-2022-1614-3796565

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-16T21:49:00', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1034dc48-ba76-47f3-a739-985b3eade6f1' | System | 17 Sep 2020 01:49:06 |
| User entered '16 Sep 2020 21:49' | System | 17 Sep 2020 01:49:06 |



FDA-CBER-2022-1614-3796566

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '16 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796567

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '17 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796568

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 3' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T11:05:11', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5197433e-c091-4aff-83b7-eb4f4742738a' | System | 18 Sep 2020 15:05:35 |
| User entered 'None (1)' | System | 18 Sep 2020 15:05:35 |



FDA-CBER-2022-1614-3796570

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T11:05:15', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5197433e-c091-4aff-83b7-eb4f4742738a' | System | 18 Sep 2020 15:05:35 |
| User entered 'No (N)' | System | 18 Sep 2020 15:05:35 |



FDA-CBER-2022-1614-3796571

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T11:05:20', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5197433e-c091-4aff-83b7-eb4f4742738a' | System | 18 Sep 2020 15:05:35 |
| User entered 'No (N)' | System | 18 Sep 2020 15:05:35 |



FDA-CBER-2022-1614-3796572

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T11:05:27', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5197433e-c091-4aff-83b7-eb4f4742738a' | System | 18 Sep 2020 15:05:35 |
| User entered 'None (1)' | System | 18 Sep 2020 15:05:35 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T11:05:30', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5197433e-c091-4aff-83b7-eb4f4742738a' | System | 18 Sep 2020 15:05:35 |
| User entered '18 Sep 2020 11:05' | System | 18 Sep 2020 15:05:35 |



FDA-CBER-2022-1614-3796574

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '17 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796575

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '18 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796576

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 4' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796577

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T21:29:22', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5bfafe97-f10d-4433-ba2d-170cff7e2191' | System | 19 Sep 2020 01:29:53 |
| User entered 'None (1)' | System | 19 Sep 2020 01:29:53 |



FDA-CBER-2022-1614-3796578

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T21:29:28', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5bfafe97-f10d-4433-ba2d-170cff7e2191' | System | 19 Sep 2020 01:29:53 |
| User entered 'No (N)' | System | 19 Sep 2020 01:29:53 |



FDA-CBER-2022-1614-3796579

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T21:29:35', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5bfafe97-f10d-4433-ba2d-170cff7e2191' | System | 19 Sep 2020 01:29:53 |
| User entered 'No (N)' | System | 19 Sep 2020 01:29:53 |



FDA-CBER-2022-1614-3796580

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T21:29:45', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5bfafe97-f10d-4433-ba2d-170cff7e2191' | System | 19 Sep 2020 01:29:53 |
| User entered 'None (1)' | System | 19 Sep 2020 01:29:53 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T21:29:50', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5bfafe97-f10d-4433-ba2d-170cff7e2191' | System | 19 Sep 2020 01:29:53 |
| User entered '18 Sep 2020 21:29' | System | 19 Sep 2020 01:29:53 |



FDA-CBER-2022-1614-3796582

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '18 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796583

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '19 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796584

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 5' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-19T23:17:02', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '19415a0f-aad2-4990-b62d-8864c86b0bd4' | System | 20 Sep 2020 03:17:31 |
| User entered 'None (1)' | System | 20 Sep 2020 03:17:31 |



FDA-CBER-2022-1614-3796586

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-19T23:17:07', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '19415a0f-aad2-4990-b62d-8864c86b0bd4' | System | 20 Sep 2020 03:17:31 |
| User entered 'No (N)' | System | 20 Sep 2020 03:17:31 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-19T23:17:15', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '19415a0f-aad2-4990-b62d-8864c86b0bd4' | System | 20 Sep 2020 03:17:31 |
| User entered 'No (N)' | System | 20 Sep 2020 03:17:31 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-19T23:17:20', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '19415a0f-aad2-4990-b62d-8864c86b0bd4' | System | 20 Sep 2020 03:17:31 |
| User entered 'None (1)' | System | 20 Sep 2020 03:17:31 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-19T23:17:26', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '19415a0f-aad2-4990-b62d-8864c86b0bd4' | System | 20 Sep 2020 03:17:31 |
| User entered '19 Sep 2020 23:17' | System | 20 Sep 2020 03:17:31 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '19 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796591

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '20 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796592

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 6' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796593

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-20T22:05:42', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '13ce982a-5aff-437f-a968-07a4419a9962' | System | 21 Sep 2020 02:06:25 |
| User entered 'None (1)' | System | 21 Sep 2020 02:06:25 |



FDA-CBER-2022-1614-3796594

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-20T22:05:58', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '13ce982a-5aff-437f-a968-07a4419a9962' | System | 21 Sep 2020 02:06:25 |
| User entered 'No (N)' | System | 21 Sep 2020 02:06:25 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-20T22:06:12', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '13ce982a-5aff-437f-a968-07a4419a9962' | System | 21 Sep 2020 02:06:25 |
| User entered 'No (N)' | System | 21 Sep 2020 02:06:25 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-20T22:06:16', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '13ce982a-5aff-437f-a968-07a4419a9962' | System | 21 Sep 2020 02:06:25 |
| User entered 'None (1)' | System | 21 Sep 2020 02:06:25 |



FDA-CBER-2022-1614-3796597

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-20T22:06:20', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '13ce982a-5aff-437f-a968-07a4419a9962' | System | 21 Sep 2020 02:06:25 |
| User entered '20 Sep 2020 22:06' | System | 21 Sep 2020 02:06:25 |



FDA-CBER-2022-1614-3796598

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '20 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796599

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '21 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796600

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 7' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796601

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-21T22:00:41', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '0e2895a2-df46-4796-b611-3aa48b5c19f4' | System | 22 Sep 2020 02:01:07 |
| User entered 'None (1)' | System | 22 Sep 2020 02:01:07 |



FDA-CBER-2022-1614-3796602

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-21T22:00:45', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '0e2895a2-df46-4796-b611-3aa48b5c19f4' | System | 22 Sep 2020 02:01:07 |
| User entered 'No (N)' | System | 22 Sep 2020 02:01:07 |



FDA-CBER-2022-1614-3796603

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-21T22:00:48', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '0e2895a2-df46-4796-b611-3aa48b5c19f4' | System | 22 Sep 2020 02:01:07 |
| User entered 'No (N)' | System | 22 Sep 2020 02:01:07 |



FDA-CBER-2022-1614-3796604

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-21T22:00:52', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '0e2895a2-df46-4796-b611-3aa48b5c19f4' | System | 22 Sep 2020 02:01:07 |
| User entered 'None (1)' | System | 22 Sep 2020 02:01:07 |



FDA-CBER-2022-1614-3796605

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-21T22:00:57', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '0e2895a2-df46-4796-b611-3aa48b5c19f4' | System | 22 Sep 2020 02:01:07 |
| User entered '21 Sep 2020 22:00' | System | 22 Sep 2020 02:01:07 |



FDA-CBER-2022-1614-3796606

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '21 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796607

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '22 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796608

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796609

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T15:27:28', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c9c4405f-d18d-43eb-b9c8-e24dc821835d' | System | 15 Sep 2020 19:28:00 |
| User entered 'None (0)' | System | 15 Sep 2020 19:28:00 |



FDA-CBER-2022-1614-3796610

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T15:27:31', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c9c4405f-d18d-43eb-b9c8-e24dc821835d' | System | 15 Sep 2020 19:28:00 |
| User entered 'None (0)' | System | 15 Sep 2020 19:28:00 |



FDA-CBER-2022-1614-3796611

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T15:27:36', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c9c4405f-d18d-43eb-b9c8-e24dc821835d' | System | 15 Sep 2020 19:28:00 |
| User entered 'None (0)' | System | 15 Sep 2020 19:28:00 |



FDA-CBER-2022-1614-3796612

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T15:27:40', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c9c4405f-d18d-43eb-b9c8-e24dc821835d' | System | 15 Sep 2020 19:28:00 |
| User entered 'None (0)' | System | 15 Sep 2020 19:28:00 |



FDA-CBER-2022-1614-3796613

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T15:27:44', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c9c4405f-d18d-43eb-b9c8-e24dc821835d' | System | 15 Sep 2020 19:28:00 |
| User entered 'None (0)' | System | 15 Sep 2020 19:28:00 |



FDA-CBER-2022-1614-3796614

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T15:27:46', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c9c4405f-d18d-43eb-b9c8-e24dc821835d' | System | 15 Sep 2020 19:28:00 |
| User entered 'None (0)' | System | 15 Sep 2020 19:28:00 |



FDA-CBER-2022-1614-3796615

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
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) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T15:27:51', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c9c4405f-d18d-43eb-b9c8-e24dc821835d' | System | 15 Sep 2020 19:28:00 |
| User entered 'No (N)' | System | 15 Sep 2020 19:28:00 |



FDA-CBER-2022-1614-3796616

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-15T15:27:55', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c9c4405f-d18d-43eb-b9c8-e24dc821835d' | System | 15 Sep 2020 19:28:00 |
| User entered '15 Sep 2020 15:27' | System | 15 Sep 2020 19:28:00 |



FDA-CBER-2022-1614-3796617

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '15 Sep 2020 14:12' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '15 Sep 2020 16:42' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 1, after vaccination (at home)' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796620

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |



FDA-CBER-2022-1614-3796621

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |



FDA-CBER-2022-1614-3796622

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |



FDA-CBER-2022-1614-3796625

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |



FDA-CBER-2022-1614-3796626

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
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) | 26 Feb 2021 02:16:57 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |



FDA-CBER-2022-1614-3796628

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '15 Sep 2020 17:37' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796629

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '16 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796630

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 2' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-16T21:47:11', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'ebd9189a-7983-40ee-8b4a-1fc4c7167aeb' | System | 17 Sep 2020 01:48:03 |
| User entered 'None (0)' | System | 17 Sep 2020 01:48:03 |



FDA-CBER-2022-1614-3796632

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-16T21:47:18', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'ebd9189a-7983-40ee-8b4a-1fc4c7167aeb' | System | 17 Sep 2020 01:48:03 |
| User entered 'None (0)' | System | 17 Sep 2020 01:48:03 |



FDA-CBER-2022-1614-3796633

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-16T21:47:24', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'ebd9189a-7983-40ee-8b4a-1fc4c7167aeb' | System | 17 Sep 2020 01:48:03 |
| User entered 'None (0)' | System | 17 Sep 2020 01:48:03 |



FDA-CBER-2022-1614-3796634

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-16T21:47:29', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'ebd9189a-7983-40ee-8b4a-1fc4c7167aeb' | System | 17 Sep 2020 01:48:03 |
| User entered 'None (0)' | System | 17 Sep 2020 01:48:03 |



FDA-CBER-2022-1614-3796635

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-16T21:47:35', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'ebd9189a-7983-40ee-8b4a-1fc4c7167aeb' | System | 17 Sep 2020 01:48:03 |
| User entered 'None (0)' | System | 17 Sep 2020 01:48:03 |



FDA-CBER-2022-1614-3796636

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-16T21:47:38', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'ebd9189a-7983-40ee-8b4a-1fc4c7167aeb' | System | 17 Sep 2020 01:48:03 |
| User entered 'None (0)' | System | 17 Sep 2020 01:48:03 |



FDA-CBER-2022-1614-3796637

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
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) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-16T21:47:50', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'ebd9189a-7983-40ee-8b4a-1fc4c7167aeb' | System | 17 Sep 2020 01:48:03 |
| User entered 'No (N)' | System | 17 Sep 2020 01:48:03 |



FDA-CBER-2022-1614-3796638

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-16T21:47:57', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'ebd9189a-7983-40ee-8b4a-1fc4c7167aeb' | System | 17 Sep 2020 01:48:03 |
| User entered '16 Sep 2020 21:47' | System | 17 Sep 2020 01:48:03 |



FDA-CBER-2022-1614-3796639

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '16 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796640

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '17 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796641

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 3' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T11:04:12', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '7db1d917-c643-4394-8e2a-d0d6380d3ab4' | System | 18 Sep 2020 15:04:57 |
| User entered 'None (0)' | System | 18 Sep 2020 15:04:57 |



FDA-CBER-2022-1614-3796643

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T11:04:18', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '7db1d917-c643-4394-8e2a-d0d6380d3ab4' | System | 18 Sep 2020 15:04:57 |
| User entered 'None (0)' | System | 18 Sep 2020 15:04:57 |



FDA-CBER-2022-1614-3796644

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T11:04:22', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '7db1d917-c643-4394-8e2a-d0d6380d3ab4' | System | 18 Sep 2020 15:04:57 |
| User entered 'None (0)' | System | 18 Sep 2020 15:04:57 |



FDA-CBER-2022-1614-3796645

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T11:04:25', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '7db1d917-c643-4394-8e2a-d0d6380d3ab4' | System | 18 Sep 2020 15:04:57 |
| User entered 'None (0)' | System | 18 Sep 2020 15:04:57 |



FDA-CBER-2022-1614-3796646

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T11:04:28', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '7db1d917-c643-4394-8e2a-d0d6380d3ab4' | System | 18 Sep 2020 15:04:57 |
| User entered 'None (0)' | System | 18 Sep 2020 15:04:57 |



FDA-CBER-2022-1614-3796647

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T11:04:34', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '7db1d917-c643-4394-8e2a-d0d6380d3ab4' | System | 18 Sep 2020 15:04:57 |
| User entered 'None (0)' | System | 18 Sep 2020 15:04:57 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
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) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T11:04:46', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '7db1d917-c643-4394-8e2a-d0d6380d3ab4' | System | 18 Sep 2020 15:04:57 |
| User entered 'No (N)' | System | 18 Sep 2020 15:04:57 |



FDA-CBER-2022-1614-3796649

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T11:04:53', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '7db1d917-c643-4394-8e2a-d0d6380d3ab4' | System | 18 Sep 2020 15:04:57 |
| User entered '18 Sep 2020 11:04' | System | 18 Sep 2020 15:04:57 |



FDA-CBER-2022-1614-3796650

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '17 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '18 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796652

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 4' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T21:28:45', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c75b4d66-9276-4bdc-bbe0-8d4f44d02d88' | System | 19 Sep 2020 01:29:17 |
| User entered 'None (0)' | System | 19 Sep 2020 01:29:17 |



FDA-CBER-2022-1614-3796654

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T21:28:49', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c75b4d66-9276-4bdc-bbe0-8d4f44d02d88' | System | 19 Sep 2020 01:29:17 |
| User entered 'None (0)' | System | 19 Sep 2020 01:29:17 |



FDA-CBER-2022-1614-3796655

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T21:28:52', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c75b4d66-9276-4bdc-bbe0-8d4f44d02d88' | System | 19 Sep 2020 01:29:17 |
| User entered 'None (0)' | System | 19 Sep 2020 01:29:17 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T21:28:56', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c75b4d66-9276-4bdc-bbe0-8d4f44d02d88' | System | 19 Sep 2020 01:29:17 |
| User entered 'None (0)' | System | 19 Sep 2020 01:29:17 |



FDA-CBER-2022-1614-3796657

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T21:28:59', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c75b4d66-9276-4bdc-bbe0-8d4f44d02d88' | System | 19 Sep 2020 01:29:17 |
| User entered 'None (0)' | System | 19 Sep 2020 01:29:17 |



FDA-CBER-2022-1614-3796658

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T21:29:03', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c75b4d66-9276-4bdc-bbe0-8d4f44d02d88' | System | 19 Sep 2020 01:29:17 |
| User entered 'None (0)' | System | 19 Sep 2020 01:29:17 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
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) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T21:29:07', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c75b4d66-9276-4bdc-bbe0-8d4f44d02d88' | System | 19 Sep 2020 01:29:17 |
| User entered 'No (N)' | System | 19 Sep 2020 01:29:17 |



FDA-CBER-2022-1614-3796660

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-18T21:29:12', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c75b4d66-9276-4bdc-bbe0-8d4f44d02d88' | System | 19 Sep 2020 01:29:17 |
| User entered '18 Sep 2020 21:29' | System | 19 Sep 2020 01:29:17 |



FDA-CBER-2022-1614-3796661

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '18 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796662

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '19 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796663

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 5' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-19T23:17:33', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'afd3ed5b-ec8c-428b-a1e0-17c2e463a465' | System | 20 Sep 2020 03:18:06 |
| User entered 'None (0)' | System | 20 Sep 2020 03:18:06 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-19T23:17:36', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'afd3ed5b-ec8c-428b-a1e0-17c2e463a465' | System | 20 Sep 2020 03:18:06 |
| User entered 'None (0)' | System | 20 Sep 2020 03:18:06 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-19T23:17:40', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'afd3ed5b-ec8c-428b-a1e0-17c2e463a465' | System | 20 Sep 2020 03:18:06 |
| User entered 'None (0)' | System | 20 Sep 2020 03:18:06 |



FDA-CBER-2022-1614-3796667

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-19T23:17:44', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'afd3ed5b-ec8c-428b-a1e0-17c2e463a465' | System | 20 Sep 2020 03:18:06 |
| User entered 'None (0)' | System | 20 Sep 2020 03:18:06 |



FDA-CBER-2022-1614-3796668

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-19T23:17:48', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'afd3ed5b-ec8c-428b-a1e0-17c2e463a465' | System | 20 Sep 2020 03:18:06 |
| User entered 'None (0)' | System | 20 Sep 2020 03:18:06 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-19T23:17:51', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'afd3ed5b-ec8c-428b-a1e0-17c2e463a465' | System | 20 Sep 2020 03:18:06 |
| User entered 'None (0)' | System | 20 Sep 2020 03:18:06 |



FDA-CBER-2022-1614-3796670

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
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) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-19T23:17:55', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'afd3ed5b-ec8c-428b-a1e0-17c2e463a465' | System | 20 Sep 2020 03:18:06 |
| User entered 'No (N)' | System | 20 Sep 2020 03:18:06 |



FDA-CBER-2022-1614-3796671

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-19T23:17:59', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'afd3ed5b-ec8c-428b-a1e0-17c2e463a465' | System | 20 Sep 2020 03:18:06 |
| User entered '19 Sep 2020 23:17' | System | 20 Sep 2020 03:18:06 |



FDA-CBER-2022-1614-3796672

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '19 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '20 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 6' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-20T22:04:52', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5a41086c-ae1b-4b8d-8cef-7da42470b4eb' | System | 21 Sep 2020 02:05:36 |
| User entered 'None (0)' | System | 21 Sep 2020 02:05:36 |



FDA-CBER-2022-1614-3796676

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-20T22:04:55', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5a41086c-ae1b-4b8d-8cef-7da42470b4eb' | System | 21 Sep 2020 02:05:36 |
| User entered 'None (0)' | System | 21 Sep 2020 02:05:36 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-20T22:05:01', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5a41086c-ae1b-4b8d-8cef-7da42470b4eb' | System | 21 Sep 2020 02:05:36 |
| User entered 'None (0)' | System | 21 Sep 2020 02:05:36 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-20T22:05:09', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5a41086c-ae1b-4b8d-8cef-7da42470b4eb' | System | 21 Sep 2020 02:05:36 |
| User entered 'None (0)' | System | 21 Sep 2020 02:05:36 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-20T22:05:16', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5a41086c-ae1b-4b8d-8cef-7da42470b4eb' | System | 21 Sep 2020 02:05:36 |
| User entered 'None (0)' | System | 21 Sep 2020 02:05:36 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-20T22:05:19', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5a41086c-ae1b-4b8d-8cef-7da42470b4eb' | System | 21 Sep 2020 02:05:36 |
| User entered 'None (0)' | System | 21 Sep 2020 02:05:36 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
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) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-20T22:05:29', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5a41086c-ae1b-4b8d-8cef-7da42470b4eb' | System | 21 Sep 2020 02:05:36 |
| User entered 'No (N)' | System | 21 Sep 2020 02:05:36 |



FDA-CBER-2022-1614-3796682

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-20T22:05:32', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5a41086c-ae1b-4b8d-8cef-7da42470b4eb' | System | 21 Sep 2020 02:05:36 |
| User entered '20 Sep 2020 22:05' | System | 21 Sep 2020 02:05:36 |



FDA-CBER-2022-1614-3796683

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '20 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |



FDA-CBER-2022-1614-3796684

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '21 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 7' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-21T22:01:04', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '7c1fc89c-f42a-44dd-8089-d9e2b3efd3e2' | System | 22 Sep 2020 02:01:34 |
| User entered 'None (0)' | System | 22 Sep 2020 02:01:34 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-21T22:01:06', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '7c1fc89c-f42a-44dd-8089-d9e2b3efd3e2' | System | 22 Sep 2020 02:01:34 |
| User entered 'None (0)' | System | 22 Sep 2020 02:01:34 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-21T22:01:09', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '7c1fc89c-f42a-44dd-8089-d9e2b3efd3e2' | System | 22 Sep 2020 02:01:34 |
| User entered 'None (0)' | System | 22 Sep 2020 02:01:34 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-21T22:01:12', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '7c1fc89c-f42a-44dd-8089-d9e2b3efd3e2' | System | 22 Sep 2020 02:01:34 |
| User entered 'None (0)' | System | 22 Sep 2020 02:01:34 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-21T22:01:16', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '7c1fc89c-f42a-44dd-8089-d9e2b3efd3e2' | System | 22 Sep 2020 02:01:34 |
| User entered 'None (0)' | System | 22 Sep 2020 02:01:34 |



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**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-21T22:01:19', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '7c1fc89c-f42a-44dd-8089-d9e2b3efd3e2' | System | 22 Sep 2020 02:01:34 |
| User entered 'None (0)' | System | 22 Sep 2020 02:01:34 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
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) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-21T22:01:23', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '7c1fc89c-f42a-44dd-8089-d9e2b3efd3e2' | System | 22 Sep 2020 02:01:34 |
| User entered 'No (N)' | System | 22 Sep 2020 02:01:34 |



FDA-CBER-2022-1614-3796693

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-09-21T22:01:27', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '7c1fc89c-f42a-44dd-8089-d9e2b3efd3e2' | System | 22 Sep 2020 02:01:34 |
| User entered '21 Sep 2020 22:01' | System | 22 Sep 2020 02:01:34 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '21 Sep 2020 12:00' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Diary Dose 1 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '22 Sep 2020 11:59' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Safety Call Day 8 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Was Contact Attempted?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:29:23 |

**US3952094**
**Folder: Safety Call Day 8 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Date of Contact or Contact Attempt *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered '23 Sep 2020' | Nick Bart (b) (4) (b) (4) | 28 Sep 2020 15:29:23 |

**US3952094**
**Folder: Safety Call Day 8 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Please select one status for the follow-up contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Contact Made (CONTACT MADE)' | Nick Bart (b) (4) | 28 Sep 2020 15:29:23 |

**US3952094**
**Folder: Safety Call Day 8 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Comments

*If Contact Not Made, please provide Comments*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:29:23 |

**US3952094**
**Folder: Safety Call Day 8 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:29:14 |

**US3952094**
**Folder: Safety Call Day 8 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered '1' | System | 28 Sep 2020 15:29:14 |

**US3952094**
**Folder: Safety Call Day 15 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Was Contact Attempted?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:01 |
| User entered 'Yes (Y)' | Stephanie Melton (b) (4) (b) (4) | 29 Sep 2020 21:27:53 |

**US3952094**
**Folder: Safety Call Day 15 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Date of Contact or Contact Attempt *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:01 |
| User entered '29 Sep 2020' | Stephanie Melton (b) (4) (b) (4) | 29 Sep 2020 21:27:53 |

**US3952094**
**Folder: Safety Call Day 15 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Please select one status for the follow-up contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:01 |
| User entered 'Contact Made (CONTACT MADE)' | Stephanie Melton (b) (4) (b) (4) | 29 Sep 2020 21:27:53 |

**US3952094**
**Folder: Safety Call Day 15 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Comments

*If Contact Not Made, please provide Comments*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:01 |
| User entered empty. | Stephanie Melton (b) (4) (b) (4) | 29 Sep 2020 21:27:53 |



FDA-CBER-2022-1614-3796706

**US3952094**
**Folder: Safety Call Day 15 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:01 |
| User entered 'Yes (Y)' | Stephanie Melton (b) (4) (b) (4) | 29 Sep 2020 21:27:58 |

**US3952094**
**Folder: Safety Call Day 15 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 12:21:52 |
| User entered '1' | System | 29 Sep 2020 21:27:58 |



FDA-CBER-2022-1614-3796708

**US3952094**
**Folder: Safety Call Day 22 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Was Contact Attempted?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 07 Oct 2020 19:02:14 |

**US3952094**
**Folder: Safety Call Day 22 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Date of Contact or Contact Attempt *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '06 Oct 2020' | Nick Bart (b) (4) | 07 Oct 2020 19:02:14 |

**US3952094**
**Folder: Safety Call Day 22 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Please select one status for the follow-up contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Contact Made (CONTACT MADE)' | Nick Bart (b) (4) | 07 Oct 2020 19:02:14 |

**US3952094**
**Folder: Safety Call Day 22 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Comments

*If Contact Not Made, please provide Comments*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 07 Oct 2020 19:02:14 |



FDA-CBER-2022-1614-3796712

**US3952094**
**Folder: Safety Call Day 22 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:01 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 07 Oct 2020 19:02:07 |

**US3952094**
**Folder: Safety Call Day 22 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 07 Oct 2020 19:02:07 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**
Was this visit performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 14 Oct 2020 20:26:28 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**
Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '14 Oct 2020' | Nick Bart (b) (4) | 14 Oct 2020 20:26:28 |



FDA-CBER-2022-1614-3796716

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**
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 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Clinic (Clinic)' | Nick Bart (b) (4) | 14 Oct 2020 20:26:28 |



FDA-CBER-2022-1614-3796717

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**
Folder OID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'VISIT2' | System | 14 Oct 2020 20:26:28 |



FDA-CBER-2022-1614-3796718

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Timepoint

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |



FDA-CBER-2022-1614-3796719

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Were vital signs assessed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Date of assessment *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '14 Oct 2020' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Time of assessment *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '12:00' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Vital Signs Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '14 Oct 2020 12:00' | System | 14 Oct 2020 20:28:05 |



FDA-CBER-2022-1614-3796723

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '37.1' C | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |



FDA-CBER-2022-1614-3796724

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Route of measurement

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Oral (Oral)' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
If Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |



FDA-CBER-2022-1614-3796726

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Pulse *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '71' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Pulse units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'bpm' | System | 14 Oct 2020 20:28:05 |



FDA-CBER-2022-1614-3796728

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Respiratory Rate *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '14' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Respiratory Rate units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'breaths/min' | System | 14 Oct 2020 20:28:05 |



FDA-CBER-2022-1614-3796730

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Systolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '117' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Systolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'mmHg' | System | 14 Oct 2020 20:28:05 |



FDA-CBER-2022-1614-3796732

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Diastolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '61' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |



FDA-CBER-2022-1614-3796733

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (1)**
**Generated On: 10 Jun 2021 10:28:25**
Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'mmHg' | System | 14 Oct 2020 20:28:05 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Timepoint

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |



FDA-CBER-2022-1614-3796735

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Were vital signs assessed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Date of assessment *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '14 Oct 2020' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Time of assessment *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '14:08' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Vital Signs Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '14 Oct 2020 14:08' | System | 14 Oct 2020 20:28:05 |



FDA-CBER-2022-1614-3796739

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '36.7' C | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |



FDA-CBER-2022-1614-3796740

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Route of measurement

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Oral (Oral)' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
If Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |



FDA-CBER-2022-1614-3796742

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Pulse *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '69' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Pulse units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'bpm' | System | 14 Oct 2020 20:28:05 |



FDA-CBER-2022-1614-3796744

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Respiratory Rate *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '14' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Respiratory Rate units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'breaths/min' | System | 14 Oct 2020 20:28:05 |



FDA-CBER-2022-1614-3796746

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Systolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '126' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |



FDA-CBER-2022-1614-3796747

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Systolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'mmHg' | System | 14 Oct 2020 20:28:05 |



FDA-CBER-2022-1614-3796748

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Diastolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '60' | Nick Bart (b) (4) | 14 Oct 2020 20:28:05 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Vital Signs - Dosing (2)**
**Generated On: 10 Jun 2021 10:28:25**
Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'mmHg' | System | 14 Oct 2020 20:28:05 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Physical Examination**
**Generated On: 10 Jun 2021 10:28:25**
Was the physical examination performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 14 Oct 2020 20:26:47 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Physical Examination**
**Generated On: 10 Jun 2021 10:28:25**
Date of examination *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '14 Oct 2020' | Nick Bart (b) (4) | 14 Oct 2020 20:26:47 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
Was study treatment given?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Stephanie Melton (b) (4) (b) (4) | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
If No, reason not given

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Stephanie Melton (b) (4) (b) (4) | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
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 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Stephanie Melton (b) (4) (b) (4) | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
What was the study treatment?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
What was the treatment date? *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '14 Oct 2020' | Stephanie Melton (b) (4) (b) (4) | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
What was the treatment time? *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '13:03' | Stephanie Melton (b) (4) (b) (4) | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
Treatment Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '14 Oct 2020 13:03' | System | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
Which arm was used to give treatment?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Left Arm (LEFT ARM)' | Stephanie Melton (b) (4) (b) (4) | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'ONCE' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796761

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Exposure**
**Generated On: 10 Jun 2021 10:28:25**
What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'INTRAMUSCULAR' | System | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Was the sample collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 14 Oct 2020 20:28:22 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Collection date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '14 Oct 2020' | Nick Bart (b) (4) | 14 Oct 2020 20:28:22 |



FDA-CBER-2022-1614-3796764

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Collection time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '12:29' | Nick Bart (b) (4) | 14 Oct 2020 20:28:22 |



FDA-CBER-2022-1614-3796765

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Collection date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '14 Oct 2020 12:29' | System | 14 Oct 2020 20:28:22 |



FDA-CBER-2022-1614-3796766

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab**
**Generated On: 10 Jun 2021 10:28:25**
Collection date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '14 Oct 2020' | Nick Bart (b) (4) | 14 Oct 2020 20:28:38 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (1)**
**Generated On: 10 Jun 2021 10:28:25**
Lab Test

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Nick Bart (b) (4) | 14 Oct 2020 20:28:38 |



FDA-CBER-2022-1614-3796768

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (1)**
**Generated On: 10 Jun 2021 10:28:25**
Was the sample collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 14 Oct 2020 20:28:38 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (1)**
**Generated On: 10 Jun 2021 10:28:25**
Collection time *(00:00 - 23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '12:31' | Nick Bart (b) (4) | 14 Oct 2020 20:28:38 |



FDA-CBER-2022-1614-3796770

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (1)**
**Generated On: 10 Jun 2021 10:28:25**
Collection date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '14 Oct 2020 12:31' | System | 14 Oct 2020 20:28:38 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (2)**
**Generated On: 10 Jun 2021 10:28:25**
Lab Test

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Nick Bart (b) (4) | 14 Oct 2020 20:28:38 |



FDA-CBER-2022-1614-3796772

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (2)**
**Generated On: 10 Jun 2021 10:28:25**
Was the sample collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) | 14 Oct 2020 20:28:38 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (2)**
**Generated On: 10 Jun 2021 10:28:25**
Collection time *(00:00 - 23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 14 Oct 2020 20:28:38 |



FDA-CBER-2022-1614-3796774

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Central Laboratory - Nasopharyngeal Swab (2)**
**Generated On: 10 Jun 2021 10:28:25**
Collection date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 14 Oct 2020 20:28:38 |



FDA-CBER-2022-1614-3796775

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 14 Oct 2020 20:26:37 |

**US3952094**
**Folder: Visit 2 Day 29 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 14 Oct 2020 20:26:37 |



FDA-CBER-2022-1614-3796777

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T14:06:20', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '0791a10b-d7c9-41af-9d2a-a93ad24c86fd' | System | 14 Oct 2020 18:06:38 |
| User entered 'Yes (Y)' | System | 14 Oct 2020 18:06:38 |



FDA-CBER-2022-1614-3796779

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T14:06:24', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '0791a10b-d7c9-41af-9d2a-a93ad24c86fd' | System | 14 Oct 2020 18:06:38 |
| User entered '98.0' | System | 14 Oct 2020 18:06:38 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T14:06:29', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '0791a10b-d7c9-41af-9d2a-a93ad24c86fd' | System | 14 Oct 2020 18:06:38 |
| User entered 'No (N)' | System | 14 Oct 2020 18:06:38 |



FDA-CBER-2022-1614-3796781

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T14:06:32', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '0791a10b-d7c9-41af-9d2a-a93ad24c86fd' | System | 14 Oct 2020 18:06:38 |
| User entered '14 Oct 2020 14:06' | System | 14 Oct 2020 18:06:38 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '14 Oct 2020 13:23' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796783

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '14 Oct 2020 15:53' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796784

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 1, after vaccination (at home)' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796785

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T21:59:49', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '3a554764-bc0d-49c2-ba92-df6945fe6a13' | System | 15 Oct 2020 02:00:21 |
| User entered 'Yes (Y)' | System | 15 Oct 2020 02:00:21 |



FDA-CBER-2022-1614-3796786

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T21:59:59', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '3a554764-bc0d-49c2-ba92-df6945fe6a13' | System | 15 Oct 2020 02:00:21 |
| User entered '98.3' | System | 15 Oct 2020 02:00:21 |



FDA-CBER-2022-1614-3796787

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T22:00:06', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '3a554764-bc0d-49c2-ba92-df6945fe6a13' | System | 15 Oct 2020 02:00:21 |
| User entered 'No (N)' | System | 15 Oct 2020 02:00:21 |



FDA-CBER-2022-1614-3796788

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T22:00:15', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '3a554764-bc0d-49c2-ba92-df6945fe6a13' | System | 15 Oct 2020 02:00:21 |
| User entered '14 Oct 2020 22:00' | System | 15 Oct 2020 02:00:21 |



FDA-CBER-2022-1614-3796789

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '14 Oct 2020 16:48' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796790

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '15 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796791

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 2' | System | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-15T22:29:18', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '156fd855-13b5-4de2-bb45-7fc1e44a467a' | System | 16 Oct 2020 02:29:43 |
| User entered 'Yes (Y)' | System | 16 Oct 2020 02:29:43 |



FDA-CBER-2022-1614-3796793

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-15T22:29:31', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '156fd855-13b5-4de2-bb45-7fc1e44a467a' | System | 16 Oct 2020 02:29:43 |
| User entered '97.3' | System | 16 Oct 2020 02:29:43 |



FDA-CBER-2022-1614-3796794

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-15T22:29:36', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '156fd855-13b5-4de2-bb45-7fc1e44a467a' | System | 16 Oct 2020 02:29:43 |
| User entered 'No (N)' | System | 16 Oct 2020 02:29:43 |



FDA-CBER-2022-1614-3796795

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-15T22:29:40', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '156fd855-13b5-4de2-bb45-7fc1e44a467a' | System | 16 Oct 2020 02:29:43 |
| User entered '15 Oct 2020 22:29' | System | 16 Oct 2020 02:29:43 |



FDA-CBER-2022-1614-3796796

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '15 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796797

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '16 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796798

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 3' | System | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-16T23:01:18', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '42ba389a-1e65-4e03-af7b-039bfc7d3aa4' | System | 17 Oct 2020 03:01:42 |
| User entered 'Yes (Y)' | System | 17 Oct 2020 03:01:42 |



FDA-CBER-2022-1614-3796800

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-16T23:01:25', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '42ba389a-1e65-4e03-af7b-039bfc7d3aa4' | System | 17 Oct 2020 03:01:42 |
| User entered '98.0' | System | 17 Oct 2020 03:01:42 |



FDA-CBER-2022-1614-3796801

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-16T23:01:34', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '42ba389a-1e65-4e03-af7b-039bfc7d3aa4' | System | 17 Oct 2020 03:01:42 |
| User entered 'No (N)' | System | 17 Oct 2020 03:01:42 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-16T23:01:37', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '42ba389a-1e65-4e03-af7b-039bfc7d3aa4' | System | 17 Oct 2020 03:01:42 |
| User entered '16 Oct 2020 23:01' | System | 17 Oct 2020 03:01:42 |



FDA-CBER-2022-1614-3796803

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '16 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796804

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '17 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796805

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 4' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796806

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T04:07:04', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'd2781492-9f48-4ea4-8d61-057ef5447ea1' | System | 18 Oct 2020 08:07:39 |
| User entered 'Yes (Y)' | System | 18 Oct 2020 08:07:39 |



FDA-CBER-2022-1614-3796807

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T04:07:20', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'd2781492-9f48-4ea4-8d61-057ef5447ea1' | System | 18 Oct 2020 08:07:39 |
| User entered '98.3' | System | 18 Oct 2020 08:07:39 |



FDA-CBER-2022-1614-3796808

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T04:07:29', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'd2781492-9f48-4ea4-8d61-057ef5447ea1' | System | 18 Oct 2020 08:07:39 |
| User entered 'No (N)' | System | 18 Oct 2020 08:07:39 |



FDA-CBER-2022-1614-3796809

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T04:07:32', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'd2781492-9f48-4ea4-8d61-057ef5447ea1' | System | 18 Oct 2020 08:07:39 |
| User entered '18 Oct 2020 04:07' | System | 18 Oct 2020 08:07:39 |



FDA-CBER-2022-1614-3796810

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '17 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796811

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '18 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796812

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 5' | System | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T22:24:44', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '8e41ef96-eabd-42bf-b96f-5120a041a8ef' | System | 19 Oct 2020 02:25:13 |
| User entered 'Yes (Y)' | System | 19 Oct 2020 02:25:13 |



FDA-CBER-2022-1614-3796814

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T22:24:58', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '8e41ef96-eabd-42bf-b96f-5120a041a8ef' | System | 19 Oct 2020 02:25:13 |
| User entered '97.8' | System | 19 Oct 2020 02:25:13 |



FDA-CBER-2022-1614-3796815

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T22:25:04', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '8e41ef96-eabd-42bf-b96f-5120a041a8ef' | System | 19 Oct 2020 02:25:13 |
| User entered 'No (N)' | System | 19 Oct 2020 02:25:13 |



FDA-CBER-2022-1614-3796816

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T22:25:11', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '8e41ef96-eabd-42bf-b96f-5120a041a8ef' | System | 19 Oct 2020 02:25:13 |
| User entered '18 Oct 2020 22:25' | System | 19 Oct 2020 02:25:13 |



FDA-CBER-2022-1614-3796817

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '18 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796818

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '19 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796819

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 6' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796820

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-19T21:15:31', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1243f258-9152-465a-82a4-7255d1984859' | System | 20 Oct 2020 01:15:56 |
| User entered 'Yes (Y)' | System | 20 Oct 2020 01:15:56 |



FDA-CBER-2022-1614-3796821

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-19T21:15:42', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1243f258-9152-465a-82a4-7255d1984859' | System | 20 Oct 2020 01:15:56 |
| User entered '96.5' | System | 20 Oct 2020 01:15:56 |



FDA-CBER-2022-1614-3796822

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-19T21:15:47', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1243f258-9152-465a-82a4-7255d1984859' | System | 20 Oct 2020 01:15:56 |
| User entered 'No (N)' | System | 20 Oct 2020 01:15:56 |



FDA-CBER-2022-1614-3796823

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-19T21:15:52', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1243f258-9152-465a-82a4-7255d1984859' | System | 20 Oct 2020 01:15:56 |
| User entered '19 Oct 2020 21:15' | System | 20 Oct 2020 01:15:56 |



FDA-CBER-2022-1614-3796824

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '19 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796825

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '20 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796826

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 7' | System | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-21T10:22:27', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1d6517c0-cbe2-4d7f-873d-ee0878a089b6' | System | 21 Oct 2020 14:23:11 |
| User entered 'Yes (Y)' | System | 21 Oct 2020 14:23:11 |



FDA-CBER-2022-1614-3796828

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-21T10:22:39', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1d6517c0-cbe2-4d7f-873d-ee0878a089b6' | System | 21 Oct 2020 14:23:11 |
| User entered '98.2' | System | 21 Oct 2020 14:23:11 |



FDA-CBER-2022-1614-3796829

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
Was any **MEDICATION TAKEN today for pain or fever**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-21T10:23:03', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1d6517c0-cbe2-4d7f-873d-ee0878a089b6' | System | 21 Oct 2020 14:23:11 |
| User entered 'No (N)' | System | 21 Oct 2020 14:23:11 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-21T10:23:06', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1d6517c0-cbe2-4d7f-873d-ee0878a089b6' | System | 21 Oct 2020 14:23:11 |
| User entered '21 Oct 2020 10:23' | System | 21 Oct 2020 14:23:11 |



FDA-CBER-2022-1614-3796831

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '20 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796832

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Temperature_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '21 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796833

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T14:06:37', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '05a28893-21ad-472a-b2d5-f622e2aa52a6' | System | 14 Oct 2020 18:06:57 |
| User entered 'None (1)' | System | 14 Oct 2020 18:06:57 |



FDA-CBER-2022-1614-3796835

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T14:06:40', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '05a28893-21ad-472a-b2d5-f622e2aa52a6' | System | 14 Oct 2020 18:06:57 |
| User entered 'No (N)' | System | 14 Oct 2020 18:06:57 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T14:06:43', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '05a28893-21ad-472a-b2d5-f622e2aa52a6' | System | 14 Oct 2020 18:06:57 |
| User entered 'No (N)' | System | 14 Oct 2020 18:06:57 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T14:06:47', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '05a28893-21ad-472a-b2d5-f622e2aa52a6' | System | 14 Oct 2020 18:06:57 |
| User entered 'None (1)' | System | 14 Oct 2020 18:06:57 |



FDA-CBER-2022-1614-3796838

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T14:06:52', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '05a28893-21ad-472a-b2d5-f622e2aa52a6' | System | 14 Oct 2020 18:06:57 |
| User entered '14 Oct 2020 14:06' | System | 14 Oct 2020 18:06:57 |



FDA-CBER-2022-1614-3796839

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '14 Oct 2020 13:23' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796840

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '14 Oct 2020 15:53' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796841

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 1, after vaccination (at home)' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796842

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T22:00:26', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1d399056-c8a6-4cbf-849a-87996ba87881' | System | 15 Oct 2020 02:01:02 |
| User entered 'None (1)' | System | 15 Oct 2020 02:01:02 |



FDA-CBER-2022-1614-3796843

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T22:00:30', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1d399056-c8a6-4cbf-849a-87996ba87881' | System | 15 Oct 2020 02:01:02 |
| User entered 'No (N)' | System | 15 Oct 2020 02:01:02 |



FDA-CBER-2022-1614-3796844

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T22:00:44', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1d399056-c8a6-4cbf-849a-87996ba87881' | System | 15 Oct 2020 02:01:02 |
| User entered 'No (N)' | System | 15 Oct 2020 02:01:02 |



FDA-CBER-2022-1614-3796845

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T22:00:53', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1d399056-c8a6-4cbf-849a-87996ba87881' | System | 15 Oct 2020 02:01:02 |
| User entered 'None (1)' | System | 15 Oct 2020 02:01:02 |



FDA-CBER-2022-1614-3796846

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T22:00:57', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1d399056-c8a6-4cbf-849a-87996ba87881' | System | 15 Oct 2020 02:01:02 |
| User entered '14 Oct 2020 22:00' | System | 15 Oct 2020 02:01:02 |



FDA-CBER-2022-1614-3796847

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '14 Oct 2020 16:48' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796848

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '15 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796849

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 2' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796850

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-15T22:29:54', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '44052dfe-1fe8-4281-a90c-0107c95a4b4f' | System | 16 Oct 2020 02:30:19 |
| User entered 'None (1)' | System | 16 Oct 2020 02:30:19 |



FDA-CBER-2022-1614-3796851

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-15T22:30:00', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '44052dfe-1fe8-4281-a90c-0107c95a4b4f' | System | 16 Oct 2020 02:30:19 |
| User entered 'No (N)' | System | 16 Oct 2020 02:30:19 |



FDA-CBER-2022-1614-3796852

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-15T22:30:06', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '44052dfe-1fe8-4281-a90c-0107c95a4b4f' | System | 16 Oct 2020 02:30:19 |
| User entered 'No (N)' | System | 16 Oct 2020 02:30:19 |



FDA-CBER-2022-1614-3796853

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-15T22:30:12', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '44052dfe-1fe8-4281-a90c-0107c95a4b4f' | System | 16 Oct 2020 02:30:19 |
| User entered 'None (1)' | System | 16 Oct 2020 02:30:19 |



FDA-CBER-2022-1614-3796854

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-15T22:30:15', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '44052dfe-1fe8-4281-a90c-0107c95a4b4f' | System | 16 Oct 2020 02:30:19 |
| User entered '15 Oct 2020 22:30' | System | 16 Oct 2020 02:30:19 |



FDA-CBER-2022-1614-3796855

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '15 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796856

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '16 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796857

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 3' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796858

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-16T23:02:20', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c8670c41-b31c-4f40-9bc6-892860de0dcc' | System | 17 Oct 2020 03:02:48 |
| User entered 'None (1)' | System | 17 Oct 2020 03:02:48 |



FDA-CBER-2022-1614-3796859

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-16T23:02:29', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c8670c41-b31c-4f40-9bc6-892860de0dcc' | System | 17 Oct 2020 03:02:48 |
| User entered 'No (N)' | System | 17 Oct 2020 03:02:48 |



FDA-CBER-2022-1614-3796860

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-16T23:02:36', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c8670c41-b31c-4f40-9bc6-892860de0dcc' | System | 17 Oct 2020 03:02:48 |
| User entered 'No (N)' | System | 17 Oct 2020 03:02:48 |



FDA-CBER-2022-1614-3796861

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-16T23:02:40', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c8670c41-b31c-4f40-9bc6-892860de0dcc' | System | 17 Oct 2020 03:02:48 |
| User entered 'None (1)' | System | 17 Oct 2020 03:02:48 |



FDA-CBER-2022-1614-3796862

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-16T23:02:43', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c8670c41-b31c-4f40-9bc6-892860de0dcc' | System | 17 Oct 2020 03:02:48 |
| User entered '16 Oct 2020 23:02' | System | 17 Oct 2020 03:02:48 |



FDA-CBER-2022-1614-3796863

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '16 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796864

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '17 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796865

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 4' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796866

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T04:07:45', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '855fcbcc-9802-4752-8faa-7c30ecf2a38f' | System | 18 Oct 2020 08:08:09 |
| User entered 'None (1)' | System | 18 Oct 2020 08:08:09 |



FDA-CBER-2022-1614-3796867

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T04:07:50', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '855fcbcc-9802-4752-8faa-7c30ecf2a38f' | System | 18 Oct 2020 08:08:09 |
| User entered 'No (N)' | System | 18 Oct 2020 08:08:09 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T04:07:54', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '855fcbcc-9802-4752-8faa-7c30ecf2a38f' | System | 18 Oct 2020 08:08:09 |
| User entered 'No (N)' | System | 18 Oct 2020 08:08:09 |



FDA-CBER-2022-1614-3796869

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T04:07:58', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '855fcbcc-9802-4752-8faa-7c30ecf2a38f' | System | 18 Oct 2020 08:08:09 |
| User entered 'None (1)' | System | 18 Oct 2020 08:08:09 |



FDA-CBER-2022-1614-3796870

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T04:08:03', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '855fcbcc-9802-4752-8faa-7c30ecf2a38f' | System | 18 Oct 2020 08:08:09 |
| User entered '18 Oct 2020 04:08' | System | 18 Oct 2020 08:08:09 |



FDA-CBER-2022-1614-3796871

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '17 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796872

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '18 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796873

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 5' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796874

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T22:25:19', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '09a29532-e9a2-4ab6-9099-aba498a95acf' | System | 19 Oct 2020 02:25:45 |
| User entered 'None (1)' | System | 19 Oct 2020 02:25:45 |



FDA-CBER-2022-1614-3796875

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T22:25:29', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '09a29532-e9a2-4ab6-9099-aba498a95acf' | System | 19 Oct 2020 02:25:45 |
| User entered 'No (N)' | System | 19 Oct 2020 02:25:45 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T22:25:34', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '09a29532-e9a2-4ab6-9099-aba498a95acf' | System | 19 Oct 2020 02:25:45 |
| User entered 'No (N)' | System | 19 Oct 2020 02:25:45 |



FDA-CBER-2022-1614-3796877

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T22:25:38', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '09a29532-e9a2-4ab6-9099-aba498a95acf' | System | 19 Oct 2020 02:25:45 |
| User entered 'None (1)' | System | 19 Oct 2020 02:25:45 |



FDA-CBER-2022-1614-3796878

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T22:25:41', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '09a29532-e9a2-4ab6-9099-aba498a95acf' | System | 19 Oct 2020 02:25:45 |
| User entered '18 Oct 2020 22:25' | System | 19 Oct 2020 02:25:45 |



FDA-CBER-2022-1614-3796879

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '18 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796880

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '19 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796881

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 6' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796882

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-19T21:16:00', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '79730f0d-0cf0-4d57-84fc-d74e697cbd1c' | System | 20 Oct 2020 01:16:30 |
| User entered 'None (1)' | System | 20 Oct 2020 01:16:30 |



FDA-CBER-2022-1614-3796883

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-19T21:16:07', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '79730f0d-0cf0-4d57-84fc-d74e697cbd1c' | System | 20 Oct 2020 01:16:30 |
| User entered 'No (N)' | System | 20 Oct 2020 01:16:30 |



FDA-CBER-2022-1614-3796884

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-19T21:16:14', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '79730f0d-0cf0-4d57-84fc-d74e697cbd1c' | System | 20 Oct 2020 01:16:30 |
| User entered 'No (N)' | System | 20 Oct 2020 01:16:30 |



FDA-CBER-2022-1614-3796885

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-19T21:16:20', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '79730f0d-0cf0-4d57-84fc-d74e697cbd1c' | System | 20 Oct 2020 01:16:30 |
| User entered 'None (1)' | System | 20 Oct 2020 01:16:30 |



FDA-CBER-2022-1614-3796886

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-19T21:16:23', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '79730f0d-0cf0-4d57-84fc-d74e697cbd1c' | System | 20 Oct 2020 01:16:30 |
| User entered '19 Oct 2020 21:16' | System | 20 Oct 2020 01:16:30 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '19 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796888

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '20 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796889

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 7' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796890

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-21T10:23:11', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'cbf4de73-f46c-4bc8-91c3-c825fefc2383' | System | 21 Oct 2020 14:23:27 |
| User entered 'None (1)' | System | 21 Oct 2020 14:23:27 |



FDA-CBER-2022-1614-3796891

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **REDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-21T10:23:15', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'cbf4de73-f46c-4bc8-91c3-c825fefc2383' | System | 21 Oct 2020 14:23:27 |
| User entered 'No (N)' | System | 21 Oct 2020 14:23:27 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-21T10:23:17', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'cbf4de73-f46c-4bc8-91c3-c825fefc2383' | System | 21 Oct 2020 14:23:27 |
| User entered 'No (N)' | System | 21 Oct 2020 14:23:27 |



FDA-CBER-2022-1614-3796893

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-21T10:23:19', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'cbf4de73-f46c-4bc8-91c3-c825fefc2383' | System | 21 Oct 2020 14:23:27 |
| User entered 'None (1)' | System | 21 Oct 2020 14:23:27 |



FDA-CBER-2022-1614-3796894

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time Stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-21T10:23:22', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'cbf4de73-f46c-4bc8-91c3-c825fefc2383' | System | 21 Oct 2020 14:23:27 |
| User entered '21 Oct 2020 10:23' | System | 21 Oct 2020 14:23:27 |



FDA-CBER-2022-1614-3796895

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '20 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796896

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: Injection Site_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '21 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796897

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796898

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T14:06:56', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'ea310bfd-d967-484c-ab3e-88d59d21a533' | System | 14 Oct 2020 18:07:17 |
| User entered 'None (0)' | System | 14 Oct 2020 18:07:17 |



FDA-CBER-2022-1614-3796899

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T14:06:58', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'ea310bfd-d967-484c-ab3e-88d59d21a533' | System | 14 Oct 2020 18:07:17 |
| User entered 'None (0)' | System | 14 Oct 2020 18:07:17 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T14:07:01', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'ea310bfd-d967-484c-ab3e-88d59d21a533' | System | 14 Oct 2020 18:07:17 |
| User entered 'None (0)' | System | 14 Oct 2020 18:07:17 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T14:07:03', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'ea310bfd-d967-484c-ab3e-88d59d21a533' | System | 14 Oct 2020 18:07:17 |
| User entered 'None (0)' | System | 14 Oct 2020 18:07:17 |



FDA-CBER-2022-1614-3796902

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T14:07:06', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'ea310bfd-d967-484c-ab3e-88d59d21a533' | System | 14 Oct 2020 18:07:17 |
| User entered 'None (0)' | System | 14 Oct 2020 18:07:17 |



FDA-CBER-2022-1614-3796903

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T14:07:08', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'ea310bfd-d967-484c-ab3e-88d59d21a533' | System | 14 Oct 2020 18:07:17 |
| User entered 'None (0)' | System | 14 Oct 2020 18:07:17 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
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) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T14:07:10', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'ea310bfd-d967-484c-ab3e-88d59d21a533' | System | 14 Oct 2020 18:07:17 |
| User entered 'No (N)' | System | 14 Oct 2020 18:07:17 |



FDA-CBER-2022-1614-3796905

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T14:07:13', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'ea310bfd-d967-484c-ab3e-88d59d21a533' | System | 14 Oct 2020 18:07:17 |
| User entered '14 Oct 2020 14:07' | System | 14 Oct 2020 18:07:17 |



FDA-CBER-2022-1614-3796906

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '14 Oct 2020 13:23' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796907

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/1)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '14 Oct 2020 15:53' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796908

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 1, after vaccination (at home)' | System | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T22:01:06', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'cfb8c82a-0a42-45f6-be4c-6de1f1bb7dc7' | System | 15 Oct 2020 02:01:55 |
| User entered 'None (0)' | System | 15 Oct 2020 02:01:55 |



FDA-CBER-2022-1614-3796910

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T22:01:10', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'cfb8c82a-0a42-45f6-be4c-6de1f1bb7dc7' | System | 15 Oct 2020 02:01:55 |
| User entered 'None (0)' | System | 15 Oct 2020 02:01:55 |



FDA-CBER-2022-1614-3796911

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T22:01:16', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'cfb8c82a-0a42-45f6-be4c-6de1f1bb7dc7' | System | 15 Oct 2020 02:01:55 |
| User entered 'None (0)' | System | 15 Oct 2020 02:01:55 |



FDA-CBER-2022-1614-3796912

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T22:01:21', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'cfb8c82a-0a42-45f6-be4c-6de1f1bb7dc7' | System | 15 Oct 2020 02:01:55 |
| User entered 'None (0)' | System | 15 Oct 2020 02:01:55 |



FDA-CBER-2022-1614-3796913

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T22:01:28', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'cfb8c82a-0a42-45f6-be4c-6de1f1bb7dc7' | System | 15 Oct 2020 02:01:55 |
| User entered 'None (0)' | System | 15 Oct 2020 02:01:55 |



FDA-CBER-2022-1614-3796914

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T22:01:35', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'cfb8c82a-0a42-45f6-be4c-6de1f1bb7dc7' | System | 15 Oct 2020 02:01:55 |
| User entered 'None (0)' | System | 15 Oct 2020 02:01:55 |



FDA-CBER-2022-1614-3796915

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
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) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T22:01:45', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'cfb8c82a-0a42-45f6-be4c-6de1f1bb7dc7' | System | 15 Oct 2020 02:01:55 |
| User entered 'No (N)' | System | 15 Oct 2020 02:01:55 |



FDA-CBER-2022-1614-3796916

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-14T22:01:49', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'cfb8c82a-0a42-45f6-be4c-6de1f1bb7dc7' | System | 15 Oct 2020 02:01:55 |
| User entered '14 Oct 2020 22:01' | System | 15 Oct 2020 02:01:55 |



FDA-CBER-2022-1614-3796917

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '14 Oct 2020 16:48' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796918

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(1/2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '15 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796919

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 2' | System | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-15T22:30:20', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1220de9f-6ce4-4833-83e9-5476e1374305' | System | 16 Oct 2020 02:31:01 |
| User entered 'None (0)' | System | 16 Oct 2020 02:31:01 |



FDA-CBER-2022-1614-3796921

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-15T22:30:24', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1220de9f-6ce4-4833-83e9-5476e1374305' | System | 16 Oct 2020 02:31:01 |
| User entered 'None (0)' | System | 16 Oct 2020 02:31:01 |



FDA-CBER-2022-1614-3796922

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-15T22:30:28', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1220de9f-6ce4-4833-83e9-5476e1374305' | System | 16 Oct 2020 02:31:01 |
| User entered 'None (0)' | System | 16 Oct 2020 02:31:01 |



FDA-CBER-2022-1614-3796923

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-15T22:30:33', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1220de9f-6ce4-4833-83e9-5476e1374305' | System | 16 Oct 2020 02:31:01 |
| User entered 'None (0)' | System | 16 Oct 2020 02:31:01 |



FDA-CBER-2022-1614-3796924

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-15T22:30:36', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1220de9f-6ce4-4833-83e9-5476e1374305' | System | 16 Oct 2020 02:31:01 |
| User entered 'None (0)' | System | 16 Oct 2020 02:31:01 |



FDA-CBER-2022-1614-3796925

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-15T22:30:39', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1220de9f-6ce4-4833-83e9-5476e1374305' | System | 16 Oct 2020 02:31:01 |
| User entered 'None (0)' | System | 16 Oct 2020 02:31:01 |



FDA-CBER-2022-1614-3796926

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
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) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-15T22:30:51', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1220de9f-6ce4-4833-83e9-5476e1374305' | System | 16 Oct 2020 02:31:01 |
| User entered 'No (N)' | System | 16 Oct 2020 02:31:01 |



FDA-CBER-2022-1614-3796927

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-15T22:30:56', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '1220de9f-6ce4-4833-83e9-5476e1374305' | System | 16 Oct 2020 02:31:01 |
| User entered '15 Oct 2020 22:30' | System | 16 Oct 2020 02:31:01 |



FDA-CBER-2022-1614-3796928

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '15 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796929

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(2)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '16 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796930

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 3' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796931

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-16T23:02:49', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'a248034c-e0c3-4f67-a04c-334bdcc9545e' | System | 17 Oct 2020 03:03:26 |
| User entered 'None (0)' | System | 17 Oct 2020 03:03:26 |



FDA-CBER-2022-1614-3796932

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-16T23:02:52', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'a248034c-e0c3-4f67-a04c-334bdcc9545e' | System | 17 Oct 2020 03:03:26 |
| User entered 'None (0)' | System | 17 Oct 2020 03:03:26 |



FDA-CBER-2022-1614-3796933

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-16T23:02:56', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'a248034c-e0c3-4f67-a04c-334bdcc9545e' | System | 17 Oct 2020 03:03:26 |
| User entered 'None (0)' | System | 17 Oct 2020 03:03:26 |



FDA-CBER-2022-1614-3796934

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-16T23:02:58', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'a248034c-e0c3-4f67-a04c-334bdcc9545e' | System | 17 Oct 2020 03:03:26 |
| User entered 'None (0)' | System | 17 Oct 2020 03:03:26 |



FDA-CBER-2022-1614-3796935

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-16T23:03:03', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'a248034c-e0c3-4f67-a04c-334bdcc9545e' | System | 17 Oct 2020 03:03:26 |
| User entered 'None (0)' | System | 17 Oct 2020 03:03:26 |



FDA-CBER-2022-1614-3796936

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-16T23:03:08', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'a248034c-e0c3-4f67-a04c-334bdcc9545e' | System | 17 Oct 2020 03:03:26 |
| User entered 'None (0)' | System | 17 Oct 2020 03:03:26 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
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) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-16T23:03:18', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'a248034c-e0c3-4f67-a04c-334bdcc9545e' | System | 17 Oct 2020 03:03:26 |
| User entered 'No (N)' | System | 17 Oct 2020 03:03:26 |



FDA-CBER-2022-1614-3796938

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-16T23:03:21', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'a248034c-e0c3-4f67-a04c-334bdcc9545e' | System | 17 Oct 2020 03:03:26 |
| User entered '16 Oct 2020 23:03' | System | 17 Oct 2020 03:03:26 |



FDA-CBER-2022-1614-3796939

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '16 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796940

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(3)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '17 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796941

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 4' | System | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T04:08:09', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '79da9b94-611e-48e3-b468-576b557dbe47' | System | 18 Oct 2020 08:08:41 |
| User entered 'None (0)' | System | 18 Oct 2020 08:08:41 |



FDA-CBER-2022-1614-3796943

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T04:08:12', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '79da9b94-611e-48e3-b468-576b557dbe47' | System | 18 Oct 2020 08:08:41 |
| User entered 'None (0)' | System | 18 Oct 2020 08:08:41 |



FDA-CBER-2022-1614-3796944

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T04:08:15', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '79da9b94-611e-48e3-b468-576b557dbe47' | System | 18 Oct 2020 08:08:41 |
| User entered 'None (0)' | System | 18 Oct 2020 08:08:41 |



FDA-CBER-2022-1614-3796945

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T04:08:19', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '79da9b94-611e-48e3-b468-576b557dbe47' | System | 18 Oct 2020 08:08:41 |
| User entered 'None (0)' | System | 18 Oct 2020 08:08:41 |



FDA-CBER-2022-1614-3796946

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T04:08:23', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '79da9b94-611e-48e3-b468-576b557dbe47' | System | 18 Oct 2020 08:08:41 |
| User entered 'None (0)' | System | 18 Oct 2020 08:08:41 |



FDA-CBER-2022-1614-3796947

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T04:08:27', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '79da9b94-611e-48e3-b468-576b557dbe47' | System | 18 Oct 2020 08:08:41 |
| User entered 'None (0)' | System | 18 Oct 2020 08:08:41 |



FDA-CBER-2022-1614-3796948

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
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) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T04:08:32', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '79da9b94-611e-48e3-b468-576b557dbe47' | System | 18 Oct 2020 08:08:41 |
| User entered 'No (N)' | System | 18 Oct 2020 08:08:41 |



FDA-CBER-2022-1614-3796949

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T04:08:35', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '79da9b94-611e-48e3-b468-576b557dbe47' | System | 18 Oct 2020 08:08:41 |
| User entered '18 Oct 2020 04:08' | System | 18 Oct 2020 08:08:41 |



FDA-CBER-2022-1614-3796950

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '17 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(4)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '18 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796952

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 5' | System | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T22:25:49', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '0fda48d6-4852-4b88-982d-9bafbe81ea9f' | System | 19 Oct 2020 02:26:19 |
| User entered 'None (0)' | System | 19 Oct 2020 02:26:19 |



FDA-CBER-2022-1614-3796954

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T22:25:53', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '0fda48d6-4852-4b88-982d-9bafbe81ea9f' | System | 19 Oct 2020 02:26:19 |
| User entered 'None (0)' | System | 19 Oct 2020 02:26:19 |



FDA-CBER-2022-1614-3796955

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T22:25:56', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '0fda48d6-4852-4b88-982d-9bafbe81ea9f' | System | 19 Oct 2020 02:26:19 |
| User entered 'None (0)' | System | 19 Oct 2020 02:26:19 |



FDA-CBER-2022-1614-3796956

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T22:26:00', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '0fda48d6-4852-4b88-982d-9bafbe81ea9f' | System | 19 Oct 2020 02:26:19 |
| User entered 'None (0)' | System | 19 Oct 2020 02:26:19 |



FDA-CBER-2022-1614-3796957

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T22:26:04', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '0fda48d6-4852-4b88-982d-9bafbe81ea9f' | System | 19 Oct 2020 02:26:19 |
| User entered 'None (0)' | System | 19 Oct 2020 02:26:19 |



FDA-CBER-2022-1614-3796958

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T22:26:07', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '0fda48d6-4852-4b88-982d-9bafbe81ea9f' | System | 19 Oct 2020 02:26:19 |
| User entered 'None (0)' | System | 19 Oct 2020 02:26:19 |



FDA-CBER-2022-1614-3796959

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
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) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T22:26:11', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '0fda48d6-4852-4b88-982d-9bafbe81ea9f' | System | 19 Oct 2020 02:26:19 |
| User entered 'No (N)' | System | 19 Oct 2020 02:26:19 |



FDA-CBER-2022-1614-3796960

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-18T22:26:16', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '0fda48d6-4852-4b88-982d-9bafbe81ea9f' | System | 19 Oct 2020 02:26:19 |
| User entered '18 Oct 2020 22:26' | System | 19 Oct 2020 02:26:19 |



FDA-CBER-2022-1614-3796961

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '18 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(5)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '19 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796963

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 6' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796964

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-19T21:16:32', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '2e4c3bea-b9e8-44bb-8d6a-6d1e7edef6ee' | System | 20 Oct 2020 01:17:01 |
| User entered 'None (0)' | System | 20 Oct 2020 01:17:01 |



FDA-CBER-2022-1614-3796965

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-19T21:16:35', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '2e4c3bea-b9e8-44bb-8d6a-6d1e7edef6ee' | System | 20 Oct 2020 01:17:01 |
| User entered 'None (0)' | System | 20 Oct 2020 01:17:01 |



FDA-CBER-2022-1614-3796966

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-19T21:16:38', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '2e4c3bea-b9e8-44bb-8d6a-6d1e7edef6ee' | System | 20 Oct 2020 01:17:01 |
| User entered 'None (0)' | System | 20 Oct 2020 01:17:01 |



FDA-CBER-2022-1614-3796967

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-19T21:16:42', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '2e4c3bea-b9e8-44bb-8d6a-6d1e7edef6ee' | System | 20 Oct 2020 01:17:01 |
| User entered 'None (0)' | System | 20 Oct 2020 01:17:01 |



FDA-CBER-2022-1614-3796968

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-19T21:16:46', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '2e4c3bea-b9e8-44bb-8d6a-6d1e7edef6ee' | System | 20 Oct 2020 01:17:01 |
| User entered 'None (0)' | System | 20 Oct 2020 01:17:01 |



FDA-CBER-2022-1614-3796969

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-19T21:16:50', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '2e4c3bea-b9e8-44bb-8d6a-6d1e7edef6ee' | System | 20 Oct 2020 01:17:01 |
| User entered 'None (0)' | System | 20 Oct 2020 01:17:01 |



FDA-CBER-2022-1614-3796970

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
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) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-19T21:16:54', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '2e4c3bea-b9e8-44bb-8d6a-6d1e7edef6ee' | System | 20 Oct 2020 01:17:01 |
| User entered 'No (N)' | System | 20 Oct 2020 01:17:01 |



FDA-CBER-2022-1614-3796971

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-19T21:16:58', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '2e4c3bea-b9e8-44bb-8d6a-6d1e7edef6ee' | System | 20 Oct 2020 01:17:01 |
| User entered '19 Oct 2020 21:16' | System | 20 Oct 2020 01:17:01 |



FDA-CBER-2022-1614-3796972

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '19 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796973

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(6)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '20 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796974

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 14 Oct 2020 18:00:44 |
| User entered 'Day 7' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796975

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**HEADACHE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-21T10:23:30', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5d1e90f0-21ae-46c0-bc52-7e4350190c01' | System | 21 Oct 2020 14:23:54 |
| User entered 'None (0)' | System | 21 Oct 2020 14:23:54 |



FDA-CBER-2022-1614-3796976

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**FATIGUE**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-21T10:23:32', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5d1e90f0-21ae-46c0-bc52-7e4350190c01' | System | 21 Oct 2020 14:23:54 |
| User entered 'None (0)' | System | 21 Oct 2020 14:23:54 |



FDA-CBER-2022-1614-3796977

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-21T10:23:34', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5d1e90f0-21ae-46c0-bc52-7e4350190c01' | System | 21 Oct 2020 14:23:54 |
| User entered 'None (0)' | System | 21 Oct 2020 14:23:54 |



FDA-CBER-2022-1614-3796978

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-21T10:23:36', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5d1e90f0-21ae-46c0-bc52-7e4350190c01' | System | 21 Oct 2020 14:23:54 |
| User entered 'None (0)' | System | 21 Oct 2020 14:23:54 |



FDA-CBER-2022-1614-3796979

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**NAUSEA/VOMITING**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-21T10:23:38', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5d1e90f0-21ae-46c0-bc52-7e4350190c01' | System | 21 Oct 2020 14:23:54 |
| User entered 'None (0)' | System | 21 Oct 2020 14:23:54 |



FDA-CBER-2022-1614-3796980

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
**CHILLS**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-21T10:23:41', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5d1e90f0-21ae-46c0-bc52-7e4350190c01' | System | 21 Oct 2020 14:23:54 |
| User entered 'None (0)' | System | 21 Oct 2020 14:23:54 |



FDA-CBER-2022-1614-3796981

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
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) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-21T10:23:44', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5d1e90f0-21ae-46c0-bc52-7e4350190c01' | System | 21 Oct 2020 14:23:54 |
| User entered 'No (N)' | System | 21 Oct 2020 14:23:54 |



FDA-CBER-2022-1614-3796982

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Time stamp

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-10-21T10:23:50', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '5d1e90f0-21ae-46c0-bc52-7e4350190c01' | System | 21 Oct 2020 14:23:54 |
| User entered '21 Oct 2020 10:23' | System | 21 Oct 2020 14:23:54 |



FDA-CBER-2022-1614-3796983

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '20 Oct 2020 12:00' | System | 14 Oct 2020 18:00:44 |

**US3952094**
**Folder: Diary Dose 2 (1)**
**Form: General_Day(7)**
**Generated On: 10 Jun 2021 10:28:25**
PC Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| User entered '21 Oct 2020 11:59' | System | 14 Oct 2020 18:00:44 |



FDA-CBER-2022-1614-3796985

**US3952094**
**Folder: Safety Call Day 36 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Was Contact Attempted?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | Nick Bart (b) (4) | 03 Nov 2020 19:11:15 |

**US3952094**
**Folder: Safety Call Day 36 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Date of Contact or Contact Attempt *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 03 Nov 2020 19:11:15 |

**US3952094**
**Folder: Safety Call Day 36 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Please select one status for the follow-up contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 03 Nov 2020 19:11:15 |

**US3952094**
**Folder: Safety Call Day 36 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Comments

*If Contact Not Made, please provide Comments*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 03 Nov 2020 19:11:15 |



FDA-CBER-2022-1614-3796989

**US3952094**
**Folder: Safety Call Day 36 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 03 Nov 2020 19:11:21 |

**US3952094**
**Folder: Safety Call Day 36 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 03 Nov 2020 19:11:21 |

**US3952094**
**Folder: Safety Call Day 43 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Was Contact Attempted?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 11NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 24 Dec 2020 11:14:34 |
| Query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 11NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' answered with 'done' (Site from DM). | Nick Bart (b) (4) | 22 Dec 2020 15:17:12 |
| User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 11NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 18 Nov 2020 15:30:45 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 03 Nov 2020 19:11:30 |



FDA-CBER-2022-1614-3796992

**US3952094**
**Folder: Safety Call Day 43 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Date of Contact or Contact Attempt *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered '28 Oct 2020' | Nick Bart (b) (4) | 03 Nov 2020 19:11:30 |

**US3952094**
**Folder: Safety Call Day 43 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Please select one status for the follow-up contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered 'Contact Made (CONTACT MADE)' | Nick Bart (b) (4) | 03 Nov 2020 19:11:30 |



FDA-CBER-2022-1614-3796994

**US3952094**
**Folder: Safety Call Day 43 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Comments

*If Contact Not Made, please provide Comments*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered empty. | Nick Bart (b) (4) | 03 Nov 2020 19:11:30 |



FDA-CBER-2022-1614-3796995

**US3952094**
**Folder: Safety Call Day 43 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 03 Nov 2020 19:11:40 |



FDA-CBER-2022-1614-3796996

**US3952094**
**Folder: Safety Call Day 43 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 03 Nov 2020 19:11:40 |



FDA-CBER-2022-1614-3796997

**US3952094**
**Folder: Safety Call Day 50 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Was Contact Attempted?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:51:00 |

**US3952094**
**Folder: Safety Call Day 50 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Date of Contact or Contact Attempt *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered '04 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:51:00 |

**US3952094**
**Folder: Safety Call Day 50 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Please select one status for the follow-up contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 10 Dec 2020 23:51:00 |

**US3952094**
**Folder: Safety Call Day 50 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Comments

*If Contact Not Made, please provide Comments*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered empty. | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:51:00 |



FDA-CBER-2022-1614-3797001

**US3952094**
**Folder: Safety Call Day 50 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:51:06 |

**US3952094**
**Folder: Safety Call Day 50 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 10 Dec 2020 23:51:06 |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**
Was this visit performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 10 Dec 2020 23:51:53 |



FDA-CBER-2022-1614-3797004

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**
Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered '11 Nov 2020' | (b) (4), (b) (6) | 10 Dec 2020 23:51:53 |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**
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 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:51:53 |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Visit Date**
**Generated On: 10 Jun 2021 10:28:25**
Folder OID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered 'VISIT3' | System | 10 Dec 2020 23:51:53 |



FDA-CBER-2022-1614-3797007

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Were vital signs assessed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | (b) (4), (b) (6) | 10 Dec 2020 23:54:59 |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Date of assessment *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered empty. | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:54:59 |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Time of assessment *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered empty. | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:54:59 |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Vital Signs Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 10 Dec 2020 23:54:59 |



FDA-CBER-2022-1614-3797011

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Temperature *(xxx.x)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered empty. | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:54:59 |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Route of measurement

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered empty. | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:54:59 |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
If Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered empty. | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:54:59 |



FDA-CBER-2022-1614-3797014

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Pulse *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered empty. | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:54:59 |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Pulse units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 10 Dec 2020 23:54:59 |



FDA-CBER-2022-1614-3797016

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Respiratory Rate *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered empty. | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:54:59 |



FDA-CBER-2022-1614-3797017

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Respiratory Rate units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 10 Dec 2020 23:54:59 |



FDA-CBER-2022-1614-3797018

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Systolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered empty. | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:54:59 |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Systolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 10 Dec 2020 23:54:59 |



FDA-CBER-2022-1614-3797020

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Diastolic Blood Pressure *(xxx)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered empty. | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:54:59 |



FDA-CBER-2022-1614-3797021

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 10 Dec 2020 23:54:59 |



FDA-CBER-2022-1614-3797022

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Height (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797023

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Vital Signs**
**Generated On: 10 Jun 2021 10:28:25**
Weight (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797024

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Physical Examination**
**Generated On: 10 Jun 2021 10:28:25**
Was the physical examination performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered 'No (N)' | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:55:16 |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Physical Examination**
**Generated On: 10 Jun 2021 10:28:25**
Date of examination *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered empty. | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:55:16 |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Was the sample collected?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:55:43 |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Collection date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered '11 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:55:43 |



FDA-CBER-2022-1614-3797028

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Collection time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered '10:22' | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:55:43 |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Immunogenicity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Collection date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '11 Nov 2020 10:22' | System | 10 Dec 2020 23:55:43 |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 19 Feb 2021 21:16:41 |
| User entered 'Yes (Y)' | (b) (4)<br>(b) (4), (b) (6) | 10 Dec 2020 23:55:51 |

**US3952094**
**Folder: Visit 3 Day 57 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 10 Dec 2020 23:55:51 |



FDA-CBER-2022-1614-3797032

**US3952094**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered 'Day 64' | System | 15 Sep 2020 19:15:58 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-11-18T16:31:08', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c5116037-4775-454e-a4d1-415142efc3ad' | System | 18 Nov 2020 21:31:30 |
| User entered 'No (N)' | System | 18 Nov 2020 21:31:30 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Have you been exposed to someone with 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 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-11-18T16:31:18', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c5116037-4775-454e-a4d1-415142efc3ad' | System | 18 Nov 2020 21:31:30 |
| User entered 'No (N)' | System | 18 Nov 2020 21:31:30 |

**US3952094**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-11-18T16:31:25', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'c5116037-4775-454e-a4d1-415142efc3ad' | System | 18 Nov 2020 21:31:30 |
| User entered '18 Nov 2020 16:31:25' | System | 18 Nov 2020 21:31:30 |

**US3952094**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered '15 Nov 2020 00:01' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:16:57 |
| Data entry locked. | System | 15 Sep 2020 19:15:58 |
| User entered '19 Nov 2020 23:59' | System | 15 Sep 2020 19:15:58 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered 'Day 68' | System | 20 Nov 2020 08:39:07 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Have you been exposed to someone with 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Fever (Temperature ≥ 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797045

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797046

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797047

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797048

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797049

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Muscle aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797050

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Body aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797051

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797052

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
New loss of taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797053

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
New loss of smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Sore throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797056

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Runny nose

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797057

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797058

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797059

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797060

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '19 Nov 2020 00:01' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '23 Nov 2020 23:59' | System | 20 Nov 2020 08:39:07 |



FDA-CBER-2022-1614-3797066

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered 'Day 75' | System | 20 Nov 2020 08:39:07 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-11-27T06:46:19', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '52badb5f-6e9b-45f2-a3d4-d004faa4b742' | System | 27 Nov 2020 11:46:40 |
| User entered 'No (N)' | System | 27 Nov 2020 11:46:40 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Have you been exposed to someone with 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) | 28 Apr 2021 00:12:42 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-11-27T06:46:27', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '52badb5f-6e9b-45f2-a3d4-d004faa4b742' | System | 27 Nov 2020 11:46:40 |
| User entered 'No (N)' | System | 27 Nov 2020 11:46:40 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-11-27T06:46:36', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '52badb5f-6e9b-45f2-a3d4-d004faa4b742' | System | 27 Nov 2020 11:46:40 |
| User entered '27 Nov 2020 06:46:36' | System | 27 Nov 2020 11:46:40 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '26 Nov 2020 00:01' | System | 20 Nov 2020 08:39:07 |



FDA-CBER-2022-1614-3797071

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '30 Nov 2020 23:59' | System | 20 Nov 2020 08:39:07 |



FDA-CBER-2022-1614-3797072

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 08:39:07 |



FDA-CBER-2022-1614-3797073

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-12-03T12:46:23', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '03675e6e-a460-4c22-8f0a-c9e2a3b99b2a' | System | 03 Dec 2020 17:46:37 |
| User entered 'No (N)' | System | 03 Dec 2020 17:46:37 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Have you been exposed to someone with 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) | 28 Apr 2021 00:12:42 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-12-03T12:46:28', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '03675e6e-a460-4c22-8f0a-c9e2a3b99b2a' | System | 03 Dec 2020 17:46:37 |
| User entered 'No (N)' | System | 03 Dec 2020 17:46:37 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-12-03T12:46:33', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '03675e6e-a460-4c22-8f0a-c9e2a3b99b2a' | System | 03 Dec 2020 17:46:37 |
| User entered '03 Dec 2020 12:46:33' | System | 03 Dec 2020 17:46:37 |



FDA-CBER-2022-1614-3797076

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '03 Dec 2020 00:01' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '07 Dec 2020 23:59' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 08:39:07 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-12-14T15:30:30', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'e7cadbd8-3127-4836-a073-f02481261aa6' | System | 14 Dec 2020 20:30:44 |
| User entered 'No (N)' | System | 14 Dec 2020 20:30:44 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Have you been exposed to someone with 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) | 28 Apr 2021 00:12:42 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-12-14T15:30:36', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'e7cadbd8-3127-4836-a073-f02481261aa6' | System | 14 Dec 2020 20:30:44 |
| User entered 'No (N)' | System | 14 Dec 2020 20:30:44 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-12-14T15:30:40', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: 'e7cadbd8-3127-4836-a073-f02481261aa6' | System | 14 Dec 2020 20:30:44 |
| User entered '14 Dec 2020 15:30:40' | System | 14 Dec 2020 20:30:44 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '10 Dec 2020 00:01' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '14 Dec 2020 23:59' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 08:39:07 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-12-21T08:40:47', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '740651dd-6e0b-42bf-bb3c-49a9fbd83621' | System | 21 Dec 2020 13:41:08 |
| User entered 'No (N)' | System | 21 Dec 2020 13:41:08 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Have you been exposed to someone with 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) | 28 Apr 2021 00:12:42 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-12-21T08:40:56', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '740651dd-6e0b-42bf-bb3c-49a9fbd83621' | System | 21 Dec 2020 13:41:08 |
| User entered 'No (N)' | System | 21 Dec 2020 13:41:08 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d8a916f3899c8f92)', Time: '2020-12-21T08:41:02', User OID: 'PatientReportedOutcome (US3952094)', ODM File OID: '740651dd-6e0b-42bf-bb3c-49a9fbd83621' | System | 21 Dec 2020 13:41:08 |
| User entered '21 Dec 2020 08:41:02' | System | 21 Dec 2020 13:41:08 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '17 Dec 2020 00:01' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '21 Dec 2020 23:59' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 08:39:07 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Have you been exposed to someone with 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Fever (Temperature ≥ 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797097

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797098

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797099

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797101

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Muscle aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797102

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Body aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797103

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797104

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
New loss of taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797105

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
New loss of smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797106

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Sore throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Runny nose

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797110

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797111

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797112

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797116

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '24 Dec 2020 00:01' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '28 Dec 2020 23:59' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 08:39:07 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Have you been exposed to someone with 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Fever (Temperature ≥ 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797125

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797126

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797129

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Muscle aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797130

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Body aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797131

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797132

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
New loss of taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797133

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
New loss of smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Sore throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797136

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Runny nose

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797138

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797139

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797140

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797144

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '31 Dec 2020 00:01' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '04 Jan 2021 23:59' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 08:39:07 |



FDA-CBER-2022-1614-3797147

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Have you been exposed to someone with 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Fever (Temperature ≥ 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797153

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797155

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797156

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797157

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Muscle aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Body aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797160

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
New loss of taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
New loss of smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Sore throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797164

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Runny nose

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797166

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797167

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797168

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '07 Jan 2021 00:01' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '11 Jan 2021 23:59' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 08:39:07 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Have you been exposed to someone with 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Fever (Temperature ≥ 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797181

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797182

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797183

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797184

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797185

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Muscle aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797186

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Body aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797187

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797188

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
New loss of taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
New loss of smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Sore throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797192

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Runny nose

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797193

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797194

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797195

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797196

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797200

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '14 Jan 2021 00:01' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '18 Jan 2021 23:59' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 08:39:07 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Have you been exposed to someone with 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Fever (Temperature ≥ 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797209

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797210

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797211

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797212

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797213

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Muscle aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797214

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Body aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797215

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797216

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
New loss of taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797217

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
New loss of smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Sore throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797220

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Runny nose

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797221

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797222

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797223

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797224

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '21 Jan 2021 00:01' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '25 Jan 2021 23:59' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
**TIMEPOINT**

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 08:39:07 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Have you been exposed to someone with 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Fever (Temperature ≥ 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797237

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797239

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797240

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797241

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Muscle aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Body aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797243

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797244

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
New loss of taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
New loss of smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Sore throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797248

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Runny nose

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797249

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797250

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797251

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797252

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

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) | 28 Apr 2021 00:12:42 |

**US3952094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:28:25**

Please 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) | 28 Apr 2021 00:12:42 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Date and time of submission

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |



FDA-CBER-2022-1614-3797256

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Open Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '28 Jan 2021 00:01' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: New Safety Follow Up Diary (1)**
**Form: Safety Follow Up Diary**
**Generated On: 10 Jun 2021 10:28:25**
Patient Cloud Close Date & Time

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:39:07 |
| Amendment Manager: User entered '01 Feb 2021 23:59' | System | 20 Nov 2020 08:39:07 |

**US3952094**
**Folder: Safety Call Day 85 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Was Contact Attempted?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:43:12 |
| User entered 'Yes (Y)' | (b) (4)<br>(b) (4), (b) (6) | 14 Dec 2020 18:08:30 |

**US3952094**
**Folder: Safety Call Day 85 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Date of Contact or Contact Attempt *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:43:12 |
| User entered '10 Dec 2020' | (b) (4)<br>(b) (4), (b) (6) | 14 Dec 2020 18:08:30 |

**US3952094**
**Folder: Safety Call Day 85 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Please select one status for the follow-up contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:43:12 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 14 Dec 2020 18:08:30 |

**US3952094**
**Folder: Safety Call Day 85 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Comments

*If Contact Not Made, please provide Comments*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:43:12 |
| User entered empty. | (b) (4)<br>(b) (4), (b) (6) | 14 Dec 2020 18:08:30 |

**US3952094**
**Folder: Safety Call Day 85 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:43:12 |
| User entered 'Yes (Y)' | (b) (4)<br>(b) (4), (b) (6) | 14 Dec 2020 18:08:34 |

**US3952094**
**Folder: Safety Call Day 85 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 14 Dec 2020 18:08:34 |



FDA-CBER-2022-1614-3797264

**US3952094**
**Folder: Safety Call Day 119 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Was Contact Attempted?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:49:27 |
| User entered 'No (N)' | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 19:21:35 |

**US3952094**
**Folder: Safety Call Day 119 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Date of Contact or Contact Attempt *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:49:27 |
| User entered empty. | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 19:21:35 |

**US3952094**
**Folder: Safety Call Day 119 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Please select one status for the follow-up contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:49:27 |
| User entered empty. | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 19:21:35 |

**US3952094**
**Folder: Safety Call Day 119 (1)**
**Form: Safety Call**
**Generated On: 10 Jun 2021 10:28:25**
Comments

*If Contact Not Made, please provide Comments*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:49:27 |
| User entered empty. | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 19:21:35 |

**US3952094**
**Folder: Safety Call Day 119 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Is the participant continuing to the next visit?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:49:27 |
| User entered 'No (N)' | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 19:21:39 |

**US3952094**
**Folder: Safety Call Day 119 (1)**
**Form: Continuing**
**Generated On: 10 Jun 2021 10:28:25**
Continuing Flag

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 26 Mar 2021 19:21:39 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: COVID-19 Contact**
**Generated On: 10 Jun 2021 10:28:25**
Date of Contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:32:09 |
| User entered '07 Jan 2021' | Nick Bart (b) (4) | 07 Jan 2021 16:12:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: COVID-19 Contact**
**Generated On: 10 Jun 2021 10:28:25**
Time of Contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:32:09 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Jan 2021 16:38:32 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Jan 2021 16:38:32 |
| User entered '10:30' reason for change: Data Entry Error | Nick Bart (b) (4) | 07 Jan 2021 16:38:32 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 07 Jan 2021 16:12:59 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:12:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: COVID-19 Contact**
**Generated On: 10 Jun 2021 10:28:25**
Date and Time of Contact (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '07 Jan 2021 10:30' | System | 07 Jan 2021 16:38:32 |
| User entered empty. | System | 07 Jan 2021 16:12:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: COVID-19 Contact**
**Generated On: 10 Jun 2021 10:28:25**
Type of Contact

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:32:09 |
| User entered 'Convalescent Tele-visit (Convalescent Tele-visit)' | Nick Bart (b) (4) | 07 Jan 2021 16:12:59 |



FDA-CBER-2022-1614-3797274

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: COVID-19 Contact**
**Generated On: 10 Jun 2021 10:28:25**
Has the subject reported symptoms of SARS-COV-2?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:32:09 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 07 Jan 2021 16:12:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User closed query 'Per CDM: Please check for record number 1 to 28 symptom days are duplicate with different symptom dates. Kindly review the data and update as appropriate else clarify. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 13 Apr 2021 09:16:31 |
| Query 'Per CDM: Please check for record number 1 to 28 symptom days are duplicate with different symptom dates. Kindly review the data and update as appropriate else clarify. Thank you. ' answered with 'Per PI Day 1 07 JAN 2021 start of Convalescent period. Correct as entered.' (Site from DM). | (b) (4), (b) (6) | 12 Apr 2021 16:20:32 |
| User opened query 'Per CDM: Please check for record number 1 to 28 symptom days are duplicate with different symptom dates. Kindly review the data and update as appropriate else clarify. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 12 Apr 2021 11:00:22 |
| User closed query 'PER CDM: For record numbers 1 & 28, duplicate entries were recorded for symptom days (Day 1 to Day 14). Please review and update the symptom days as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 12 Apr 2021 10:57:58 |
| Query 'PER CDM: For record numbers 1 & 28, duplicate entries were recorded for symptom days (Day 1 to Day 14). Please review and update the symptom days as appropriate. Thank you.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 19:00:44 |
| User opened query 'PER CDM: For record numbers 1 & 28, duplicate entries were recorded for symptom days (Day 1 to Day 14). Please review and update the symptom days as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 22 Mar 2021 07:49:21 |
| User entered 'Day 1 (Day 1)' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |



FDA-CBER-2022-1614-3797276

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered '22 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '24 Dec 2020' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered '0' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 00:32:46 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered '1' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '0' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 21:46:00 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:27:17 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:27:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 19:31:30 |
| User closed query 'Per CDM: Per sponsor review, please provide a response to O2 Saturation for all log lines. Thank you.' (Site from DM). | (b) (4), (b) (6) | 12 Apr 2021 10:58:08 |
| Query 'Per CDM: Per sponsor review, please provide a response to O2 Saturation for all log lines. Thank you.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 18:59:34 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Apr 2021 18:59:01 |
| User entered '89' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 18:59:01 |
| User opened query 'Per CDM: Per sponsor review, please provide a response to O2 Saturation for all log lines. Thank you.' (Site from DM). | (b) (4), (b) (6) | 24 Feb 2021 15:03:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:27:17 |
| User entered empty. | System | 12 Apr 2021 23:41:24 |
| User entered '%' | System | 09 Apr 2021 18:59:01 |
| User entered empty. | System | 07 Jan 2021 16:25:38 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 21:46:09 |
| DataPoint Un-verified. | Atanas Filev (b) (4) | 13 Apr 2021 01:27:17 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) | 13 Apr 2021 01:27:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) | 12 Apr 2021 23:41:24 |
| User closed query 'Per Progress note on 31Dec20, subject experienced fever of 39.0 C. Please confirm and update if needed.' (Site from CRA). | (b) (4), (b) (6) | 21 Jan 2021 15:32:38 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:32:36 |
| Query 'Per Progress note on 31Dec20, subject experienced fever of 39.0 C. Please confirm and update if needed.' answered with 'updated' (Site from CRA). | Nick Bart (b) (4) | 20 Jan 2021 15:56:08 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 20 Jan 2021 15:56:02 |
| User entered '39.0' C reason for change: Data Entry Error | Nick Bart (b) (4) | 20 Jan 2021 15:56:02 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 20 Jan 2021 15:55:56 |
| User entered '39.0' (non-conformant). | Nick Bart (b) (4) | 20 Jan 2021 15:55:56 |
| User opened query 'Per Progress note on 31Dec20, subject experienced fever of 39.0 C. Please confirm and update if needed.' (Site from CRA). | (b) (4), (b) (6) | 07 Jan 2021 17:12:24 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 07 Jan 2021 17:11:42 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 21:46:07 |
| User closed query 'Please enter Not Done for this and all other assessments.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 21:46:04 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| Query 'Please enter Not Done for this and all other assessments.' answered with 'Updated. ' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:27:24 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:27:17 |
| User opened query 'Please enter Not Done for this and all other assessments.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 01:15:04 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:14:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 00:32:46 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 00:32:46 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 21:46:10 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:27:17 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:15:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:27:17 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:15:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:27:17 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:15:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:27:17 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:15:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:27:17 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:15:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:27:17 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:15:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:27:17 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:15:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:27:17 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:15:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:27:17 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:15:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:27:17 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:15:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:27:17 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:15:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |



FDA-CBER-2022-1614-3797296

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:27:17 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:15:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (1)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:27:17 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:15:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:41:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:25:38 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 2 (Day 2)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered '23 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '25 Dec 2020' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered '0' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 00:33:05 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered '1' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '0' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:28:09 |
| User entered empty. | System | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 00:33:05 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 00:33:05 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |



FDA-CBER-2022-1614-3797315

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (2)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:31 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:39:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:13 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 3 (Day 3)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:37:56 |
| User entered '24 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:37:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '26 Dec 2020' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '0' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:37:56 |
| User entered '89' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:37:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 12 Apr 2021 23:37:56 |
| User entered empty. | System | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:37:56 |
| User entered '39.0' C reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:37:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:37:56 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:37:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:37:56 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:37:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:37:56 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:37:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |



FDA-CBER-2022-1614-3797340

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (3)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:34 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 4 (Day 4)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:37:01 |
| User entered '25 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:37:01 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '27 Dec 2020' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |



FDA-CBER-2022-1614-3797344

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '0' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:32:25 |
| User entered empty. | System | 07 Jan 2021 16:26:58 |



FDA-CBER-2022-1614-3797347

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:41:15 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 00:38:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |



FDA-CBER-2022-1614-3797352

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |



FDA-CBER-2022-1614-3797354

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |



FDA-CBER-2022-1614-3797357

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |



FDA-CBER-2022-1614-3797359

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (4)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:26:58 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 5 (Day 5)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:33:37 |
| User entered '26 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:33:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '28 Dec 2020' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '0' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |



FDA-CBER-2022-1614-3797367

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:32:25 |
| User entered empty. | System | 07 Jan 2021 16:27:25 |



FDA-CBER-2022-1614-3797369

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |



FDA-CBER-2022-1614-3797376

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |



FDA-CBER-2022-1614-3797380

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |



FDA-CBER-2022-1614-3797381

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |



FDA-CBER-2022-1614-3797382

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (5)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:25 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 6 (Day 6)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered '27 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:36:39 |
| User entered '25 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:36:00 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:33:07 |
| User entered '27 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:33:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '29 Dec 2020' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '0' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:32:25 |
| User entered empty. | System | 07 Jan 2021 16:27:47 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |



FDA-CBER-2022-1614-3797395

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |



FDA-CBER-2022-1614-3797397

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |



FDA-CBER-2022-1614-3797404

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |



FDA-CBER-2022-1614-3797406

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (6)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:27:47 |



FDA-CBER-2022-1614-3797408

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 7 (Day 7)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:32:42 |
| User entered '28 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:32:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '30 Dec 2020' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '0' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |



FDA-CBER-2022-1614-3797411

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 21:44:32 |
| User closed query 'Per Med rec, O2 sat was 96%.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 21:44:31 |
| Query 'Per Med rec, O2 sat was 96%.' answered with 'Updated.' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:43 |
| User entered '96' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:33 |
| User opened query 'Per Med rec, O2 sat was 96%.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 01:09:47 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:09:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:28:33 |
| User entered empty. | System | 07 Jan 2021 16:28:05 |



FDA-CBER-2022-1614-3797413

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 21:45:12 |
| User closed query 'Per med rec, temp was 36.8 C.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 21:44:34 |
| Query 'Per med rec, temp was 36.8 C.' answered with 'Updated. ' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:44 |
| User entered '36.8' C reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:28:33 |
| User opened query 'Per med rec, temp was 36.8 C.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 01:10:12 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:09:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |



FDA-CBER-2022-1614-3797420

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |



FDA-CBER-2022-1614-3797421

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |



FDA-CBER-2022-1614-3797422

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |



FDA-CBER-2022-1614-3797424

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |



FDA-CBER-2022-1614-3797426

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |



FDA-CBER-2022-1614-3797429

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (7)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 8 (Day 8)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:32:09 |
| User entered '29 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:32:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '31 Dec 2020' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |



FDA-CBER-2022-1614-3797432

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '0' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |



FDA-CBER-2022-1614-3797433

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:32:25 |
| User entered empty. | System | 07 Jan 2021 16:28:30 |



FDA-CBER-2022-1614-3797435

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |



FDA-CBER-2022-1614-3797437

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |



FDA-CBER-2022-1614-3797439

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |



FDA-CBER-2022-1614-3797442

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |



FDA-CBER-2022-1614-3797443

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |



FDA-CBER-2022-1614-3797444

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:31:59 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:31:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |



FDA-CBER-2022-1614-3797446

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |



FDA-CBER-2022-1614-3797447

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |



FDA-CBER-2022-1614-3797448

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |



FDA-CBER-2022-1614-3797450

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |



FDA-CBER-2022-1614-3797451

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (8)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:28:30 |



FDA-CBER-2022-1614-3797452

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 9 (Day 9)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered '30 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:30:52 |
| User entered '29 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:30:05 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:29:28 |
| User entered '30 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:29:28 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '01 Jan 2021' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '0' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:32:25 |
| User entered empty. | System | 07 Jan 2021 16:29:16 |



FDA-CBER-2022-1614-3797457

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |



FDA-CBER-2022-1614-3797461

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |



FDA-CBER-2022-1614-3797466

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |



FDA-CBER-2022-1614-3797467

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:29:28 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:29:28 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |



FDA-CBER-2022-1614-3797470

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |



FDA-CBER-2022-1614-3797471

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |



FDA-CBER-2022-1614-3797473

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (9)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:16 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 10 (Day 10)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:28:51 |
| User entered '31 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:28:51 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '02 Jan 2021' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |



FDA-CBER-2022-1614-3797476

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '0' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |



FDA-CBER-2022-1614-3797477

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:32:25 |
| User entered empty. | System | 07 Jan 2021 16:29:46 |



FDA-CBER-2022-1614-3797479

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |



FDA-CBER-2022-1614-3797482

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |



FDA-CBER-2022-1614-3797483

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |



FDA-CBER-2022-1614-3797486

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |



FDA-CBER-2022-1614-3797488

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |



FDA-CBER-2022-1614-3797490

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |



FDA-CBER-2022-1614-3797491

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |



FDA-CBER-2022-1614-3797492

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |



FDA-CBER-2022-1614-3797494

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:28:51 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:28:51 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |



FDA-CBER-2022-1614-3797495

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (10)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:29:46 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 11 (Day 11)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User closed query 'Per CDM: Per sponsor review, please confirm date.' (Site from DM). | (b) (4), (b) (6) | 13 Apr 2021 08:44:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:28:04 |
| User entered '01 Jan 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:28:04 |
| Query 'Per CDM: Per sponsor review, please confirm date.' answered with 'correct as entered' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 19:05:43 |
| User opened query 'Per CDM: Per sponsor review, please confirm date.' (Site from DM). | (b) (4), (b) (6) | 24 Feb 2021 13:55:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '03 Jan 2020' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '0' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:32:25 |
| User entered empty. | System | 07 Jan 2021 16:30:15 |



FDA-CBER-2022-1614-3797501

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |



FDA-CBER-2022-1614-3797505

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |



FDA-CBER-2022-1614-3797506

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |



FDA-CBER-2022-1614-3797508

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |



FDA-CBER-2022-1614-3797513

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |



FDA-CBER-2022-1614-3797514

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |



FDA-CBER-2022-1614-3797516

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:28:04 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:28:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |



FDA-CBER-2022-1614-3797517

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (11)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 12 (Day 12)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:27:39 |
| User entered '02 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:27:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '04 Jan 2021' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |



FDA-CBER-2022-1614-3797520

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '0' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:32:25 |
| User entered empty. | System | 07 Jan 2021 16:30:35 |



FDA-CBER-2022-1614-3797523

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |



FDA-CBER-2022-1614-3797526

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |



FDA-CBER-2022-1614-3797527

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |



FDA-CBER-2022-1614-3797530

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |



FDA-CBER-2022-1614-3797531

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |



FDA-CBER-2022-1614-3797534

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |



FDA-CBER-2022-1614-3797536

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |



FDA-CBER-2022-1614-3797537

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |



FDA-CBER-2022-1614-3797539

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (12)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:30:35 |



FDA-CBER-2022-1614-3797540

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 13 (Day 13)' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:25:29 |
| User entered '03 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:25:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '05 Jan 2021' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |



FDA-CBER-2022-1614-3797542

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '0' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |



FDA-CBER-2022-1614-3797543

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:32:25 |
| User entered empty. | System | 07 Jan 2021 16:31:05 |



FDA-CBER-2022-1614-3797545

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |



FDA-CBER-2022-1614-3797548

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |



FDA-CBER-2022-1614-3797549

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |



FDA-CBER-2022-1614-3797551

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:10 |
| User closed query 'Please enter data.' (Site from CRA). | (b) (4), (b) (6) | 21 Jan 2021 15:33:08 |
| Query 'Please enter data.' answered with 'updated' (Site from CRA). | Nick Bart (b) (4) | 20 Jan 2021 15:55:40 |
| User entered 'None (None)' reason for change: Data Entry Error | Nick Bart (b) (4) | 20 Jan 2021 15:55:35 |
| User opened query 'Please enter data.' (Site from CRA). | (b) (4), (b) (6) | 07 Jan 2021 17:10:33 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 07 Jan 2021 17:10:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |



FDA-CBER-2022-1614-3797556

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |



FDA-CBER-2022-1614-3797558

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |



FDA-CBER-2022-1614-3797561

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (13)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:31:05 |



FDA-CBER-2022-1614-3797562

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 14 (Day 14)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:24:46 |
| User entered '04 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:24:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '06 Jan 2021' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '0' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |



FDA-CBER-2022-1614-3797565

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:32:25 |
| User entered empty. | System | 07 Jan 2021 16:32:15 |



FDA-CBER-2022-1614-3797567

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |



FDA-CBER-2022-1614-3797571

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |



FDA-CBER-2022-1614-3797572

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |



FDA-CBER-2022-1614-3797573

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |



FDA-CBER-2022-1614-3797575

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |



FDA-CBER-2022-1614-3797578

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |



FDA-CBER-2022-1614-3797580

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:24:46 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:24:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |



FDA-CBER-2022-1614-3797583

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (14)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:15 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 15 (Day 15)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:11:04 |
| User entered 'Day 1 (Day 1)' reason for change: Data Entry Error | Nick Bart (b) (4) | 20 Jan 2021 16:02:02 |
| User entered 'Day 15 (Day 15)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |



FDA-CBER-2022-1614-3797585

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:23:44 |
| User entered '05 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:23:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '07 Jan 2021' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |



FDA-CBER-2022-1614-3797586

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '0' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 21:46:25 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:23:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:23:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Nick Bart (b) (4) | 07 Jan 2021 16:33:40 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:32:25 |
| User entered empty. | System | 12 Apr 2021 23:23:44 |
| User entered '%' | System | 07 Jan 2021 16:33:40 |
| User entered empty. | System | 07 Jan 2021 16:32:36 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 21:46:26 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:23:44 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:23:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered '98.6' F reason for change: Data Entry Error | Nick Bart (b) (4) | 07 Jan 2021 16:33:40 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |



FDA-CBER-2022-1614-3797590

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |



FDA-CBER-2022-1614-3797593

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |



FDA-CBER-2022-1614-3797594

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |



FDA-CBER-2022-1614-3797596

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |



FDA-CBER-2022-1614-3797601

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |



FDA-CBER-2022-1614-3797602

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |



FDA-CBER-2022-1614-3797604

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 21:46:33 |
| User closed query 'Per progress note, subject had diarhea on 5Jan' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 21:46:31 |
| Query 'Per progress note, subject had diarhea on 5Jan' answered with 'Updated. ' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:59 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:34:52 |
| User opened query 'Per progress note, subject had diarhea on 5Jan' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 00:45:54 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 00:45:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (15)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:03:06 |
| User entered 'None (None)' | Nick Bart (b) (4) | 07 Jan 2021 16:32:36 |



FDA-CBER-2022-1614-3797606

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 16 (Day 16)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:11:04 |
| User entered 'Day 2 (Day 2)' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:23:09 |
| User entered '06 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:23:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '08 Jan 2021' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797608

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '0' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797609

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty; reason for change Data Entry Error | Nick Bart (b) (4) | 20 Jan 2021 16:03:48 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Nick Bart (b) (4) | 20 Jan 2021 16:03:30 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797610

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:32:25 |
| User entered empty. | System | 20 Jan 2021 16:03:48 |
| User entered '%' | System | 20 Jan 2021 16:03:30 |
| User entered empty. | System | 20 Jan 2021 16:02:33 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:32:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:23:09 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:23:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '37.8' C reason for change: Data Entry Error | Nick Bart (b) (4) | 20 Jan 2021 16:03:20 |
| User entered '98.6' F | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797612

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797614

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797615

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797616

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797617

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797618

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797619

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797620

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797621

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797622

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797623

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797624

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797625

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797626

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (16)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:02:33 |



FDA-CBER-2022-1614-3797628

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 17 (Day 17)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:11:04 |
| User entered 'Day 3 (Day 3)' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797629

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:21:53 |
| User entered '07 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:21:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '09 Jan 2021' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797630

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '0' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797631

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:21:53 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:21:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 12 Apr 2021 23:21:53 |
| User entered empty. | System | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797633

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:21:53 |
| User entered '98.6' F reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:21:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered missing code ND - Not Done. | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797634

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797635

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797636

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:21:53 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:21:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797638

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797639

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797640

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797641

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797642

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797643

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797644

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797645

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797646

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797647

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797648

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797649

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (17)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:05:21 |



FDA-CBER-2022-1614-3797650

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 18 (Day 18)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:11:04 |
| User entered 'Day 4 (Day 4)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:21:04 |
| User entered '08 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:21:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '10 Jan 2021' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797652

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '0' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797653

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 21:47:25 |
| User closed query 'Please add O2 Sat as 96%' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 21:47:24 |
| Query 'Please add O2 Sat as 96%' answered with 'Updated. ' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:42:39 |
| User entered '96' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:42:33 |
| User opened query 'Please add O2 Sat as 96%' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 01:03:27 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:03:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:42:33 |
| User entered empty. | System | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797655

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:21:04 |
| User entered '37.8' C reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:21:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '102.2' F | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797656

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797657

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797658

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 22:05:29 |
| User closed query 'Please enter "Mild" shortness of breath.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 21:47:28 |
| Query 'Please enter "Mild" shortness of breath.' answered with 'Updated. ' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:42:41 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:42:33 |
| User opened query 'Please enter "Mild" shortness of breath.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 00:48:05 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 00:47:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797660

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797661

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797662

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797663

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797664

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797665

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797666

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797667

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797668

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797669

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797670

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797671

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (18)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:00 |



FDA-CBER-2022-1614-3797672

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 19 (Day 19)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:11:04 |
| User entered 'Day 5 (Day 5)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:20:21 |
| User entered '09 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:20:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '11 Jan 2021' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797674

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '0' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797675

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797676

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797677

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:20:21 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:20:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '98.0' F | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797678

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797680

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797681

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797682

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797683

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797684

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797685

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797686

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797687

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797688

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797690

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797691

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797692

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797693

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (19)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:06:30 |



FDA-CBER-2022-1614-3797694

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 20 (Day 20)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:11:04 |
| User entered 'Day 6 (Day 6)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:19:48 |
| User entered '10 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:19:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '12 Jan 2021' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |



FDA-CBER-2022-1614-3797696

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '0' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |



FDA-CBER-2022-1614-3797697

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |



FDA-CBER-2022-1614-3797698

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 20 Jan 2021 16:07:00 |



FDA-CBER-2022-1614-3797699

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:19:42 |
| User entered '102.2' F reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:19:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '98.6' F | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |



FDA-CBER-2022-1614-3797701

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |



FDA-CBER-2022-1614-3797702

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:19:42 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:19:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |



FDA-CBER-2022-1614-3797703

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |



FDA-CBER-2022-1614-3797704

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |



FDA-CBER-2022-1614-3797705

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |



FDA-CBER-2022-1614-3797706

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |



FDA-CBER-2022-1614-3797708

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |



FDA-CBER-2022-1614-3797709

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |



FDA-CBER-2022-1614-3797710

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |



FDA-CBER-2022-1614-3797712

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |



FDA-CBER-2022-1614-3797713

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |



FDA-CBER-2022-1614-3797715

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (20)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:00 |



FDA-CBER-2022-1614-3797716

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 21 (Day 21)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:11:04 |
| User entered 'Day 7 (Day 7)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:19:01 |
| User entered '11 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:19:01 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '13 Jan 2021' | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |



FDA-CBER-2022-1614-3797718

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) | 12 Apr 2021 23:18:54 |
| User entered '0' reason for change: Data Entry Error | Atanas Filev (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '1' | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |



FDA-CBER-2022-1614-3797720

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 20 Jan 2021 16:07:12 |



FDA-CBER-2022-1614-3797721

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| User entered '98' F reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |



FDA-CBER-2022-1614-3797728

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |



FDA-CBER-2022-1614-3797735

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |



FDA-CBER-2022-1614-3797736

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (21)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:18:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:12 |



FDA-CBER-2022-1614-3797738

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 22 (Day 22)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:10:21 |
| User entered 'Day 8 (Day 8)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:17:43 |
| User entered '12 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:17:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '14 Jan 2021' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '0' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |



FDA-CBER-2022-1614-3797741

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |



FDA-CBER-2022-1614-3797742

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 20 Jan 2021 16:07:46 |



FDA-CBER-2022-1614-3797743

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:17:43 |
| User entered '98.6' F reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:17:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered missing code ND - Not Done. | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |



FDA-CBER-2022-1614-3797745

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |



FDA-CBER-2022-1614-3797746

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:17:43 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:17:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 19:32:20 |
| User closed query 'Please have PI fill in source to confirm SOB was none.' (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 19:32:17 |
| Query 'Please have PI fill in source to confirm SOB was none.' answered with 'updated in source.' (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 21:44:16 |
| User entered 'Severe (Severe)' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 21:44:00 |
| User opened query 'Please have PI fill in source to confirm SOB was none.' (Site from CRA). | (b) (4), (b) (6) | 21 Jan 2021 15:40:02 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Jan 2021 15:38:28 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |



FDA-CBER-2022-1614-3797747

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |



FDA-CBER-2022-1614-3797748

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |



FDA-CBER-2022-1614-3797749

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |



FDA-CBER-2022-1614-3797751

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |



FDA-CBER-2022-1614-3797752

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |



FDA-CBER-2022-1614-3797754

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |



FDA-CBER-2022-1614-3797755

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |



FDA-CBER-2022-1614-3797756

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |



FDA-CBER-2022-1614-3797757

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |



FDA-CBER-2022-1614-3797758

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |



FDA-CBER-2022-1614-3797759

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (22)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:07:46 |



FDA-CBER-2022-1614-3797760

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 23 (Day 23)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:10:21 |
| User entered 'Day 9 (Day 9)' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |



FDA-CBER-2022-1614-3797761

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered '13 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '15 Jan 2021' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |



FDA-CBER-2022-1614-3797762

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) | 12 Apr 2021 23:16:15 |
| User entered '1' reason for change: Data Entry Error | Atanas Filev (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '0' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User closed query 'Per Med rec, subject had 98% O2 Sat.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 21:46:45 |
| Query 'Per Med rec, subject had 98% O2 Sat.' answered with 'Updated. ' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:01 |
| User entered '98' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:42:57 |
| User opened query 'Per Med rec, subject had 98% O2 Sat.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 00:59:10 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 00:58:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Jan 2021 15:40:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '96' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:42:57 |
| User entered empty. | System | 12 Apr 2021 23:16:15 |
| User entered '%' | System | 20 Jan 2021 16:08:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User closed query 'Per Med rec, subject had 39.1 C fever.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 21:46:47 |
| Query 'Per Med rec, subject had 39.1 C fever.' answered with 'Updated. ' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:03 |
| User entered '39.1' C reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:42:57 |
| User opened query 'Per Med rec, subject had 39.1 C fever.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 00:58:40 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 00:58:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:50:57 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 00:50:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 20 Jan 2021 16:08:57 |
| User entered '97.8' F reason for change: Data Entry Error | Nick Bart (b) (4) | 20 Jan 2021 16:08:57 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 20 Jan 2021 16:08:49 |
| User entered '97.8' (non-conformant). | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 21:46:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'Mild (Mild)' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (23)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered 'None (None)' | Nick Bart (b) (4) | 20 Jan 2021 16:08:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 24 (Day 24)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:10:21 |
| User entered 'Day 10 (Day 10)' | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |



FDA-CBER-2022-1614-3797783

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:06:45 |
| User entered '14 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:06:45 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '16 Jan 2021' | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |



FDA-CBER-2022-1614-3797784

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) | 12 Apr 2021 23:13:30 |
| User entered '0' reason for change: Data Entry Error | Atanas Filev (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '1' | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |



FDA-CBER-2022-1614-3797786

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 20 Jan 2021 16:09:28 |



FDA-CBER-2022-1614-3797787

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |



FDA-CBER-2022-1614-3797788

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| User entered 'Severe (Severe)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |



FDA-CBER-2022-1614-3797791

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |



FDA-CBER-2022-1614-3797801

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |



FDA-CBER-2022-1614-3797802

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (24)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:13:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:28 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 25 (Day 25)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:10:21 |
| User entered 'Day 11 (Day 11)' | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:06:45 |
| User entered '15 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:06:45 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '17 Jan 2021' | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |



FDA-CBER-2022-1614-3797806

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) | 12 Apr 2021 23:09:03 |
| User entered '0' reason for change: Data Entry Error | Atanas Filev (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '1' | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 21:47:45 |
| User closed query 'Use lower average of 85%.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 21:47:43 |
| Query 'Use lower average of 85%.' answered with 'Updated. ' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:21 |
| User entered '85' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:18 |
| User opened query 'Use lower average of 85%.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 01:01:08 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 01:00:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered '96' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 12 Apr 2021 23:09:03 |
| User entered empty. | System | 20 Jan 2021 16:09:41 |



FDA-CBER-2022-1614-3797809

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered '97.8' F reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |



FDA-CBER-2022-1614-3797810

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |



FDA-CBER-2022-1614-3797811

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |



FDA-CBER-2022-1614-3797812

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |



FDA-CBER-2022-1614-3797814

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |



FDA-CBER-2022-1614-3797815

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |



FDA-CBER-2022-1614-3797816

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |



FDA-CBER-2022-1614-3797817

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |



FDA-CBER-2022-1614-3797818

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |



FDA-CBER-2022-1614-3797820

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |



FDA-CBER-2022-1614-3797821

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |



FDA-CBER-2022-1614-3797822

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |



FDA-CBER-2022-1614-3797823

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |



FDA-CBER-2022-1614-3797824

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |



FDA-CBER-2022-1614-3797825

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (25)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:41 |



FDA-CBER-2022-1614-3797826

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 26 (Day 26)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:10:21 |
| User entered 'Day 12 (Day 12)' | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797827

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:06:45 |
| User entered '16 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:06:45 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '18 Jan 2021' | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797828

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '1' | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797829

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797830

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797831

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797832

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797833

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797835

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797836

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797837

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797838

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797839

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797840

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797841

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797842

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797843

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797844

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797845

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797846

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797847

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (26)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:09:53 |



FDA-CBER-2022-1614-3797848

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 27 (Day 27)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:10:21 |
| User entered 'Day 13 (Day 13)' | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797849

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:06:45 |
| User entered '17 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:06:45 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '19 Jan 2021' | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797850

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered '1' | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797851

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797852

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797853

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797854

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797856

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797857

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797858

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797860

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797861

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797862

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797863

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797864

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797865

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797866

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797868

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797869

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (27)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:33:49 |
| User entered empty. | Nick Bart (b) (4) | 20 Jan 2021 16:10:10 |



FDA-CBER-2022-1614-3797870

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 28 (Day 28)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:10:21 |
| User entered 'Day 14 (Day 14)' | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797871

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered '18 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:06:45 |
| User entered '20 Jan 2021' | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered '1' | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797873

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797874

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797875

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797876

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797877

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797878

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797879

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797880

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797881

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797882

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797884

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797885

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797886

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797887

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797888

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797889

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797890

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797891

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (28)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:01:53 |



FDA-CBER-2022-1614-3797892

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 29 (Day 29)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:38 |
| User entered 'Day 15 (Day 15)' | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered '19 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4)<br>(b) (4) | 12 Apr 2021 23:06:45 |
| User entered '21 Jan 2021' | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797894

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered '1' | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797896

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797897

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797898

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797901

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797902

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797903

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797904

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797905

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797906

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797907

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797908

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797909

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797910

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797911

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797912

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797913

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (29)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:14 |



FDA-CBER-2022-1614-3797914

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 30 (Day 30)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:09:38 |
| User entered 'Day 16 (Day 16)' | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered '20 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:06:45 |
| User entered '22 Jan 2021' | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered '1' | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |



FDA-CBER-2022-1614-3797917

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |



FDA-CBER-2022-1614-3797918

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 28 Jan 2021 18:02:27 |



FDA-CBER-2022-1614-3797919

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |



FDA-CBER-2022-1614-3797920

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |



FDA-CBER-2022-1614-3797923

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |



FDA-CBER-2022-1614-3797924

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |



FDA-CBER-2022-1614-3797925

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |



FDA-CBER-2022-1614-3797926

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |



FDA-CBER-2022-1614-3797927

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |



FDA-CBER-2022-1614-3797930

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |



FDA-CBER-2022-1614-3797932

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |



FDA-CBER-2022-1614-3797934

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (30)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Nick Bart (b) (4) | 28 Jan 2021 18:02:27 |



FDA-CBER-2022-1614-3797936

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 31 (Day 31)' | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797937

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered '21 Jan 2021' | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered '1' | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797939

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797940

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797941

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797942

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797944

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797945

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797948

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797949

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797951

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797952

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797953

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797954

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797955

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797956

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797957

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (31)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797958

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 32 (Day 32)' | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797959

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered '22 Jan 2021' | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered '1' | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797961

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797962

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797963

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797967

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797970

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797971

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797972

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797973

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797974

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797975

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797976

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797977

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797978

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797979

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (32)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:37:24 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:23 |



FDA-CBER-2022-1614-3797980

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 33 (Day 33)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797981

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '23 Jan 2021' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797982

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '1' | Atanas Filev (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797983

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797984

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797985

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797986

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797987

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797988

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797989

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797990

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797991

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4)<br>(b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797992

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797993

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797994

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797995

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797996

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4)<br>(b) (4) | 12 Apr 2021 23:04:40 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797998

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3797999

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |



FDA-CBER-2022-1614-3798000

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4)<br>(b) (4) | 12 Apr 2021 23:04:40 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (33)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:15 |
| DataPoint activated with code reason code Data required. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:43:47 |
| DataPoint inactivated with code reason code Data not required. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:04:40 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 34 (Day 34)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:29 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '24 Jan 2012' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:29 |



FDA-CBER-2022-1614-3798004

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '1' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:29 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:29 |



FDA-CBER-2022-1614-3798006

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 13 Apr 2021 01:44:29 |



FDA-CBER-2022-1614-3798007

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:29 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:29 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:29 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:44:29 |



FDA-CBER-2022-1614-3798011

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:29 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:29 |



FDA-CBER-2022-1614-3798013

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:29 |



FDA-CBER-2022-1614-3798014

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:29 |



FDA-CBER-2022-1614-3798015

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:29 |



FDA-CBER-2022-1614-3798016

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:44:29 |



FDA-CBER-2022-1614-3798017

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:44:29 |



FDA-CBER-2022-1614-3798018

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:44:29 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:44:29 |



FDA-CBER-2022-1614-3798020

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:29 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:29 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:29 |



FDA-CBER-2022-1614-3798023

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (34)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:29 |



FDA-CBER-2022-1614-3798024

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 35 (Day 35)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '25 Jan 2021' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '1' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:44:49 |



FDA-CBER-2022-1614-3798028

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 13 Apr 2021 01:44:49 |



FDA-CBER-2022-1614-3798029

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:44:49 |



FDA-CBER-2022-1614-3798033

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:49 |



FDA-CBER-2022-1614-3798034

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:44:49 |



FDA-CBER-2022-1614-3798036

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:44:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:44:49 |



FDA-CBER-2022-1614-3798039

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:49 |



FDA-CBER-2022-1614-3798040

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:49 |



FDA-CBER-2022-1614-3798041

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:49 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:49 |



FDA-CBER-2022-1614-3798044

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:49 |



FDA-CBER-2022-1614-3798045

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (35)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:49 |



FDA-CBER-2022-1614-3798046

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 36 (Day 36)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |



FDA-CBER-2022-1614-3798047

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '26 Jan 2021' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '0' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered '1' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '91' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 13 Apr 2021 01:49:48 |
| User entered empty. | System | 13 Apr 2021 01:44:59 |



FDA-CBER-2022-1614-3798051

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '37.8' C reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User closed query 'Could you please change this to not done.' (Site from CRA). | (b) (4), (b) (6) | 14 Apr 2021 16:53:33 |
| Query 'Could you please change this to not done.' answered with 'Updated. ' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:30:07 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:27:57 |
| User opened query 'Could you please change this to not done.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 21:53:30 |
| User entered 'None (None)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (36)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:44:59 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 37 (Day 37)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:45:12 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '27 Jan 2021' | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:45:12 |



FDA-CBER-2022-1614-3798070

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '1' | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:45:12 |



FDA-CBER-2022-1614-3798071

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 17:51:15 |
| User closed query 'O2 sat was 99% not 98%. Please update.' (Site from CRA). | (b) (4), (b) (6) | 14 Apr 2021 17:51:12 |
| Query 'O2 sat was 99% not 98%. Please update.' answered with 'Updated. ' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 17:49:19 |
| User entered '99' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 17:49:13 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User opened query 'O2 sat was 99% not 98%. Please update.' (Site from CRA). | (b) (4), (b) (6) | 14 Apr 2021 16:54:44 |
| User closed query 'O2 sat was 99%. Please add.' (Site from CRA). | (b) (4), (b) (6) | 14 Apr 2021 16:54:44 |
| Query 'O2 sat was 99%. Please add.' answered with 'Updated.' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:36:13 |
| User entered '98' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:36:06 |
| User opened query 'O2 sat was 99%. Please add.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 22:17:42 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:45:12 |



FDA-CBER-2022-1614-3798072

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 14 Apr 2021 16:36:06 |
| User entered empty. | System | 13 Apr 2021 01:45:12 |



FDA-CBER-2022-1614-3798073

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User closed query 'Temp was 36.9 C. Please add.' (Site from CRA). | (b) (4), (b) (6) | 14 Apr 2021 16:54:48 |
| Query 'Temp was 36.9 C. Please add.' answered with 'Updated.' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:36:23 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 14 Apr 2021 16:36:20 |
| User entered '36.9' C reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:36:20 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 14 Apr 2021 16:36:06 |
| User entered '36.9' (non-conformant). | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:36:06 |
| User opened query 'Temp was 36.9 C. Please add.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 22:18:01 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:45:12 |



FDA-CBER-2022-1614-3798074

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:45:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:45:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:45:12 |



FDA-CBER-2022-1614-3798077

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:45:12 |



FDA-CBER-2022-1614-3798078

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:45:12 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:45:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:45:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:45:12 |



FDA-CBER-2022-1614-3798082

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:45:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:45:12 |



FDA-CBER-2022-1614-3798084

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:45:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:45:12 |



FDA-CBER-2022-1614-3798086

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:45:12 |



FDA-CBER-2022-1614-3798087

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:45:12 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:45:12 |



FDA-CBER-2022-1614-3798089

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (37)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:45:12 |



FDA-CBER-2022-1614-3798090

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 38 (Day 38)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |



FDA-CBER-2022-1614-3798091

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '28 Jan 2012' | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '0' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User closed query 'Please remove assessment not done.' (Site from CRA). | (b) (4), (b) (6) | 14 Apr 2021 16:55:10 |
| Query 'Please remove assessment not done.' answered with 'Updated.' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:36:50 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:36:48 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:36:39 |
| User opened query 'Please remove assessment not done.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 22:16:29 |
| User entered '96' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '%' | System | 14 Apr 2021 16:36:48 |
| User entered empty. | System | 14 Apr 2021 16:36:39 |
| User entered '%' | System | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User closed query 'Please remove assessment not done.' (Site from CRA). | (b) (4), (b) (6) | 14 Apr 2021 16:55:12 |
| Query 'Please remove assessment not done.' answered with 'Updated.' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:36:52 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:36:48 |
| User entered empty; reason for change Data Entry Error | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:36:39 |
| User opened query 'Please remove assessment not done.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 22:16:35 |
| User entered '36.8' C | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |



FDA-CBER-2022-1614-3798096

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |



FDA-CBER-2022-1614-3798106

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |



FDA-CBER-2022-1614-3798111

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (38)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered 'Not Done (Not Done)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:49:48 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 39 (Day 39)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |



FDA-CBER-2022-1614-3798113

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '29 Jan 2021' | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '1' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |



FDA-CBER-2022-1614-3798116

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 13 Apr 2021 01:50:18 |



FDA-CBER-2022-1614-3798117

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |



FDA-CBER-2022-1614-3798124

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |



FDA-CBER-2022-1614-3798126

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |



FDA-CBER-2022-1614-3798128

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (39)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Symptom Day

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Day 40 (Day 40)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |



FDA-CBER-2022-1614-3798135

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '30 Jan 2021' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Assessment Not Done

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered '1' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |



FDA-CBER-2022-1614-3798138

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
O2 Saturation Units

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 13 Apr 2021 01:50:18 |



FDA-CBER-2022-1614-3798139

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Temperature

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Chills

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Cough

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Shortness of Breath

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Difficulty Breathing

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |



FDA-CBER-2022-1614-3798144

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Fatigue

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:50:18 |



FDA-CBER-2022-1614-3798146

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Body Aches

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Headache

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Taste

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:50:18 |



FDA-CBER-2022-1614-3798149

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
New Loss of Smell

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:50:18 |



FDA-CBER-2022-1614-3798150

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Nasal Congestion

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |



FDA-CBER-2022-1614-3798151

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |



FDA-CBER-2022-1614-3798152

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Nausea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Vomiting

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Diarrhea

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:50:18 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Symptom Log (40)**
**Generated On: 10 Jun 2021 10:28:25**
Sore Throat

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:55:45 |
| User entered empty. | Atanas Filev (b) (4)<br>(b) (4) | 13 Apr 2021 01:50:18 |



FDA-CBER-2022-1614-3798156

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: COVID Diagnostic Test**
**Generated On: 10 Jun 2021 10:28:25**
Date of Visit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 09 Apr 2021 20:15:44 |
| User closed query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 24JDEC2020 is recorded under Covid-19 Assessment Visit in EDC, however the sample is missing in PPD Central lab. Please confirm if the sample has been shipped and provide Accession number and Tracking details in the response. Thank you.' (Site from DM). | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 12:42:12 |
| Query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 24JDEC2020 is recorded under Covid-19 Assessment Visit in EDC, however the sample is missing in PPD Central lab. Please confirm if the sample has been shipped and provide Accession number and Tracking details in the response. Thank you.' answered with 'Covid-19 diagnostic test was run by a lab other than Study Central Lab' (Site from DM). | Nick Bart (b) (4) | 28 Jan 2021 17:49:50 |
| User opened query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 24JDEC2020 is recorded under Covid-19 Assessment Visit in EDC, however the sample is missing in PPD Central lab. Please confirm if the sample has been shipped and provide Accession number and Tracking details in the response. Thank you.' (Site from DM). | (b) (4), (b) (6) | 15 Jan 2021 08:53:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:12 |
| User entered '24 Dec 2020' | Nick Bart (b) (4) | 07 Jan 2021 16:16:37 |



FDA-CBER-2022-1614-3798157

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: COVID Diagnostic Test**
**Generated On: 10 Jun 2021 10:28:25**
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 09 Apr 2021 20:15:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:12 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 07 Jan 2021 16:16:37 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: COVID Diagnostic Test**
**Generated On: 10 Jun 2021 10:28:25**
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 09 Apr 2021 20:15:44 |
| 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) (6) | 11 Jan 2021 09:32:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:12 |
| 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 'Already entered' (Site from System). | Nick Bart (b) (4) | 07 Jan 2021 16:17:25 |
| 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 | 07 Jan 2021 16:16:37 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 07 Jan 2021 16:16:37 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: COVID Diagnostic Test**
**Generated On: 10 Jun 2021 10:28:25**
Date of Test

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User closed query 'Per CDM:RE-QUERY: Subject is tested positive, please review and reconcile if corresponding Illness visit should be updated. Thank you.' (Site from DM). | (b) (4), (b) (6) | 15 Apr 2021 06:11:59 |
| User signature succeeded. | Mimi Van Der Leden | 09 Apr 2021 20:15:44 |
| Query 'Per CDM:RE-QUERY: Subject is tested positive, please review and reconcile if corresponding Illness visit should be updated. Thank you.' answered with 'Subject was admitted to Hospital.' (Site from DM). | (b) (4)<br>(b) (4), (b) (6) | 09 Apr 2021 19:09:20 |
| User opened query 'Per CDM:RE-QUERY: Subject is tested positive, please review and reconcile if corresponding Illness visit should be updated. Thank you.' (Site from DM). | (b) (4), (b) (6) | 05 Apr 2021 12:53:28 |
| User closed query 'Per CDM: A diagnostic test has been completed, however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM). | (b) (4), (b) (6) | 05 Apr 2021 12:51:22 |
| Query 'Per CDM: A diagnostic test has been completed, however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' answered with 'Subject's last Covid-19 swab taken on 14Oct2020 and was negative. No illness visits were required for this subject.' (Site from DM). | Nick Bart (b) (4) | 02 Apr 2021 18:50:26 |
| User opened query 'Per CDM: A diagnostic test has been completed, however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM). | (b) (4), (b) (6) | 08 Mar 2021 20:22:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:12 |
| User entered '24 Dec 2020' | Nick Bart (b) (4) | 07 Jan 2021 16:16:37 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: COVID Diagnostic Test**
**Generated On: 10 Jun 2021 10:28:25**
Type of Test Performed

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 09 Apr 2021 20:15:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 17:18:48 |
| User closed query 'PER CDM: Re-Query: As per previous response it was reported as ‘Pending Medical records'. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 05 Apr 2021 12:50:50 |
| Query 'PER CDM: Re-Query: As per previous response it was reported as ‘Pending Medical records'. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' answered with 'updated' (Site from DM). | Nick Bart (b) (4) | 02 Apr 2021 18:51:38 |
| DataPoint Un-verified. | Nick Bart (b) (4) | 02 Apr 2021 18:51:34 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: Data Entry Error | Nick Bart (b) (4) | 02 Apr 2021 18:51:34 |
| User opened query 'PER CDM: Re-Query: As per previous response it was reported as ‘Pending Medical records'. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 12 Jan 2021 04:05:22 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 12 Jan 2021 04:04:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:12 |
| Query 'Data is required. Please complete.' answered with 'Pending Medical records' (Site from System). | Nick Bart (b) (4) | 07 Jan 2021 16:17:38 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 07 Jan 2021 16:16:37 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:16:37 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: COVID Diagnostic Test**
**Generated On: 10 Jun 2021 10:28:25**
Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 09 Apr 2021 20:15:44 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:20:12 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:16:37 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: COVID Diagnostic Test**
**Generated On: 10 Jun 2021 10:28:25**
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) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 09 Apr 2021 20:15:44 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:20:12 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 07 Jan 2021 16:16:37 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: COVID Diagnostic Test**
**Generated On: 10 Jun 2021 10:28:25**
Lab/ Institution Test Performed

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 09 Apr 2021 20:15:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:12 |
| User entered 'Washington Hospital Center' | Nick Bart (b) (4) | 07 Jan 2021 16:16:37 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: COVID Diagnostic Test**
**Generated On: 10 Jun 2021 10:28:25**
CLIA Certified?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 09 Apr 2021 20:15:44 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:20:12 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 07 Jan 2021 16:16:37 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: COVID Diagnostic Test**
**Generated On: 10 Jun 2021 10:28:25**
COVID-19 Positive (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 07 Jan 2021 16:16:37 |



FDA-CBER-2022-1614-3798166

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Did the subject have Respiratory Rates ≥ 30 per Minute?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| User closed query 'PER CDM: Re-Query: As per previous response it was reported as ‘pending medical records’. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 14:17:02 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 19:33:01 |
| User closed query 'Please update form as new information is now available.' (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 19:32:59 |
| Query 'Please update form as new information is now available.' answered with 'updated' (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 22:02:52 |
| Query 'PER CDM: Re-Query: As per previous response it was reported as ‘pending medical records’. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 22:02:36 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 10 Mar 2021 17:50:46 |
| User opened query 'Please update form as new information is now available.' (Site from CRA). | (b) (4), (b) (6) | 10 Mar 2021 17:50:43 |
| User opened query 'PER CDM: Re-Query: As per previous response it was reported as ‘pending medical records’. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 11 Jan 2021 14:38:05 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Jan 2021 14:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| Query 'Data is required. Please complete.' answered with 'Pending medical records' (Site from System). | Nick Bart (b) (4) | 07 Jan 2021 16:20:38 |



FDA-CBER-2022-1614-3798167

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Did the subject have Respiratory Rates ≥ 30 per Minute?

| Audit | User | Time (GMT) |
|---|---|---|
| User opened query 'Data is required. Please complete.' (Site from System). | System | 07 Jan 2021 16:20:23 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Start Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 19:33:13 |
| User entered '13 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 10 Mar 2021 17:50:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
End Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 19:33:15 |
| User entered '30 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 10 Mar 2021 17:50:51 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Respiratory Rate

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 21:07:10 |
| Query 'Per MAR, RR was 38 on 13Jan21.' canceled (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 21:07:09 |
| User opened query 'Per MAR, RR was 38 on 13Jan21.' (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 20:44:46 |
| User entered '46' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 10 Mar 2021 17:50:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Did the subject have Heart Rate ≥ 125 beats per minute

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User closed query 'PER CDM: Re-Query: As per previous response it was reported as 'pending medical records'. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 14 Apr 2021 14:17:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 20:40:01 |
| Query 'PER CDM: Re-Query: As per previous response it was reported as 'pending medical records'. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 22:05:26 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| User opened query 'PER CDM: Re-Query: As per previous response it was reported as 'pending medical records'. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 11 Jan 2021 14:38:14 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Jan 2021 14:37:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| Query 'Data is required. Please complete.' answered with 'pending medical records' (Site from System). | Nick Bart (b) (4) | 07 Jan 2021 16:20:44 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 07 Jan 2021 16:20:23 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Start Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
End Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |



FDA-CBER-2022-1614-3798174

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Heart Rate

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User closed query 'Per CDM: Per sponsor review, Did the subject have Oxygen Saturation of SpO2 < 93% is recorded as Yes. However, Symptom Log does not have record of SpO2 < 93%. Please review and reconcile.' (Site from DM). | (b) (4), (b) (6) | 14 Apr 2021 14:20:49 |
| Query 'Per CDM: Per sponsor review, Did the subject have Oxygen Saturation of SpO2 < 93% is recorded as Yes. However, Symptom Log does not have record of SpO2 < 93%. Please review and reconcile.' answered with 'SpO2 fell below 93% during end of symptom log. PI was unable to capture due to subject incapacity during this time. Medical records obtained from hospital after the fact show SpO2 falling below 93% requiring intubation.' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 22:08:42 |
| User opened query 'Per CDM: Per sponsor review, Did the subject have Oxygen Saturation of SpO2 < 93% is recorded as Yes. However, Symptom Log does not have record of SpO2 < 93%. Please review and reconcile.' (Site from DM). | (b) (4), (b) (6) | 24 Feb 2021 15:05:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Start Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 19:33:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| User entered '19 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
End Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 19:33:23 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| User entered '30 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Oxygen Saturation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:30:27 |
| User closed query 'O2 Sat 74% on 30Jan at 12:11pm.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 00:28:58 |
| Query 'O2 Sat 74% on 30Jan at 12:11pm.' answered with 'Updated per page 3 of the medical records. ' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:00:59 |
| User entered '74' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:00:41 |
| User opened query 'O2 Sat 74% on 30Jan at 12:11pm.' (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 20:58:18 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 12 Apr 2021 20:56:45 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 20:55:32 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| User entered '85' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| User closed query 'PER CDM: Re-Query: As per previous response it was reported as ‘pending medical records’. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 14:20:19 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 21:04:43 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 12 Apr 2021 21:04:33 |
| Query 'PER CDM: Re-Query: As per previous response it was reported as ‘pending medical records’. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' answered with 'Records received data unknown.' (Site from DM). | (b) (4), (b) (6) | 12 Apr 2021 15:59:50 |
| User opened query 'PER CDM: Re-Query: As per previous response it was reported as ‘pending medical records’. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 11 Jan 2021 14:38:22 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Jan 2021 14:37:28 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| Query 'Data is required. Please complete.' answered with 'Pending medical records' (Site from System). | Nick Bart (b) (4) | 07 Jan 2021 16:20:56 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 07 Jan 2021 16:20:23 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Start Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
End Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
PaO2

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Did the subject have Respiratory failure?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User closed query 'PER CDM: Re-Query: As per previous response it was reported as ‘pending medical records’. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 14 Apr 2021 14:21:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 19:35:26 |
| Query 'PER CDM: Re-Query: As per previous response it was reported as ‘pending medical records’. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 22:15:00 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| User opened query 'PER CDM: Re-Query: As per previous response it was reported as ‘pending medical records’. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 11 Jan 2021 14:38:32 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Jan 2021 14:38:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| Query 'Data is required. Please complete.' answered with 'pending medical records' (Site from System). | Nick Bart (b) (4) | 07 Jan 2021 16:21:04 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 07 Jan 2021 16:20:23 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Start Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 21:17:12 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Apr 2021 22:14:39 |
| User entered '19 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 22:14:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

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**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| User closed query 'PER CDM: Re-Query: As per previous response it was reported as ‘pending medical records’. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 14:21:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 19:35:41 |
| Query 'PER CDM: Re-Query: As per previous response it was reported as ‘pending medical records’. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 22:15:15 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| User opened query 'PER CDM: Re-Query: As per previous response it was reported as ‘pending medical records’. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 11 Jan 2021 14:38:40 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Jan 2021 14:38:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| Query 'Data is required. Please complete.' answered with 'pending medical records' (Site from System). | Nick Bart (b) (4) | 07 Jan 2021 16:21:09 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 07 Jan 2021 16:20:23 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Start Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 20:55:53 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Apr 2021 22:28:41 |
| User entered '19 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 22:28:41 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
High-Flow Oxygen?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:53:12 |
| User closed query 'High Flow Nasal Canula was place on 13Jan21. Please update.' (Site from CRA). | (b) (4), (b) (6) | 14 Apr 2021 16:52:57 |
| Query 'High Flow Nasal Canula was place on 13Jan21. Please update.' answered with 'Updated. ' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:22:20 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:22:02 |
| User opened query 'High Flow Nasal Canula was place on 13Jan21. Please update.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 22:21:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 22:20:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

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**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Start Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:53:12 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:22:02 |
| User entered '13 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:22:02 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
End Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:53:12 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:24:51 |
| User entered '19 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:24:51 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

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**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Non-Invasive Ventilation?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:53:12 |
| User closed query 'Please confirm if subject had any non-invasive ventilation.' (Site from CRA). | (b) (4), (b) (6) | 14 Apr 2021 16:53:01 |
| Query 'Please confirm if subject had any non-invasive ventilation.' answered with 'Update. ' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:25:04 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:24:18 |
| User opened query 'Please confirm if subject had any non-invasive ventilation.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 22:20:14 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 00:30:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Start Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:53:12 |
| User closed query 'Future date has been entered. Please correct.' (Site from System). | System | 14 Apr 2021 16:24:51 |
| User entered '24 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:24:51 |
| User opened query 'Future date has been entered. Please correct.' (Site from System). | System | 14 Apr 2021 16:24:18 |
| User entered '24 Dec 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:24:18 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 00:30:19 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
End Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:53:12 |
| User entered '13 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 16:24:51 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 13 Apr 2021 00:30:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Mechanical Ventilation?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:29:49 |
| User closed query 'subject had mechanical ventilation starting on 19Jan21.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 00:29:46 |
| Query 'subject had mechanical ventilation starting on 19Jan21.' answered with 'Updated.' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:37:07 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:18:32 |
| User opened query 'subject had mechanical ventilation starting on 19Jan21.' (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 21:18:51 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 12 Apr 2021 21:18:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Start Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:29:51 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:37:00 |
| User entered '19 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:37:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
End Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:29:53 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:46:55 |
| User entered '30 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 23:46:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

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**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
ECMO?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Start Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
End Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Start Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
End Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Evidence of Shock Requires Vasopressors

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Start Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
End Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Acute Renal Dysfunction?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Start Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

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**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Hepatic Dysfunction?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Start Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Neurologic Dysfunction?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Start Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Clinical Evidence

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:29:59 |
| User closed query 'Subject had Chest Xray which showed Pneumonia beginning on 25Dec20.' (Site from CRA). | (b) (4), (b) (6) | 13 Apr 2021 00:29:58 |
| Query 'Subject had Chest Xray which showed Pneumonia beginning on 25Dec20.' answered with 'Updated with start date of 24 Dec 2020. ' (Site from CRA). | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:18:49 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:18:32 |
| User opened query 'Subject had Chest Xray which showed Pneumonia beginning on 25Dec20.' (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 21:37:08 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Apr 2021 22:28:41 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 22:28:41 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |



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**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Date of Assessment

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:30:01 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:18:32 |
| User entered '24 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:18:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Radiographical Evidence

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:30:03 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:18:32 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:18:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Date of Assessment

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 00:30:06 |
| DataPoint Un-verified. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:18:32 |
| User entered '24 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:18:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Admission to an intensive care unit due to SARS-CoV-2

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 19:35:52 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 22:02:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered 'No (N)' | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Start Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 21:29:00 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Apr 2021 22:28:41 |
| User entered '19 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 22:28:41 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Covid-19 Severity Assessment**
**Generated On: 10 Jun 2021 10:28:25**
End Date

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 19:35:54 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Apr 2021 22:28:41 |
| User entered '30 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 22:28:41 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 17:20:22 |
| User entered empty. | Nick Bart (b) (4) | 07 Jan 2021 16:20:23 |

**US3952094**
**Folder: Covid-19 Assessment 07 Jan 2021**
**Form: Generate Next COVID-19 Assessment**
**Generated On: 10 Jun 2021 10:28:25**
Generate Next COVID-19 Assessment

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:49:27 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 17:31:34 |
| User entered 'No (N)' | Nick Bart (b) (4) | 11 Mar 2021 19:55:22 |



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**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events Summary**
**Generated On: 10 Jun 2021 10:28:25**
Did the participant experience any adverse events?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:10:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:21 |
| User entered 'Yes (Y)' | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:43:35 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
AEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Jan 2021 18:27:56 |
| User entered 'USA-US215-2021-mRNA-1273-P301000001' | System | 04 Jan 2021 18:27:47 |
| User entered 'New' | (b) (4), (b) (6) | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Adverse event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: SARS-CoV-2 infection - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 31 Dec 2020 20:25:19 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 31 Dec 2020 20:25:19 |
| Data point term sent to Coder | System | 31 Dec 2020 20:24:44 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 31 Dec 2020 20:24:12 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 31 Dec 2020 20:24:12 |
| User entered 'SARS-CoV-2 Infection' reason for change: Data Entry Error | Brianne Okunji (b) (4)<br>(b) (4) | 31 Dec 2020 20:24:12 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 31 Dec 2020 19:59:34 |
| User entered empty. | Brianne Okunji (b) (4)<br>(b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Was this a medically-attended AE?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered 'Yes (Y)' | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Was this a Solicited Adverse Reaction?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered 'No (N)' reason for change: Data Entry Error | Brianne Okunji (b) (4)<br>(b) (4) | 31 Dec 2020 20:24:12 |
| User entered 'Yes (Y)' | Brianne Okunji (b) (4)<br>(b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Is this event a confirmed diagnosis of Symptomatic Covid-19?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered 'Yes (Y)' | Brianne Okunji (b) (4)<br>(b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered '24 Dec 2020' reason for change: Data Entry Error | Brianne Okunji (b) (4)<br>(b) (4) | 31 Dec 2020 20:24:12 |
| User entered '23 Dec 2020' | Brianne Okunji (b) (4)<br>(b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Start time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered empty. | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
AE start date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User entered empty. | System | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 17:08:48 |
| User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | System | 16 Feb 2021 16:52:56 |
| DataPoint Un-verified. | Mimi Van Der Leden (b) (4) | 16 Feb 2021 16:52:56 |
| User entered 'No (N)' reason for change: New Information | Mimi Van Der Leden (b) (4) | 16 Feb 2021 16:52:56 |
| User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | System | 08 Feb 2021 15:44:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered 'Yes (Y)' | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, end date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 17:08:50 |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 16 Feb 2021 16:37:46 |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System). | System | 16 Feb 2021 16:37:46 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 08 Feb 2021 15:44:36 |
| DataPoint Un-verified. | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:44:36 |
| User entered '30 Jan 2021' reason for change: New Information | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:44:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered empty. | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
End time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 17:08:52 |
| User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System). | System | 16 Feb 2021 16:55:53 |
| User entered empty; reason for change Per Query Resolution | Mimi Van Der Leden (b) (4) | 16 Feb 2021 16:55:53 |
| User closed query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System). | System | 16 Feb 2021 16:52:56 |
| User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System). | System | 16 Feb 2021 16:52:56 |
| User opened query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System). | System | 08 Feb 2021 15:44:36 |
| DataPoint Un-verified. | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:44:36 |
| User entered '02:07' reason for change: New Information | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:44:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered empty. | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
AE End Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| 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. ' canceled (Site from Safety). | (b) (4), (b) (6) | 30 Apr 2021 15:12:23 |
| User entered empty. | System | 16 Feb 2021 16:55:53 |
| User entered '30 Jan 2021 02:07' | System | 08 Feb 2021 15:44:36 |
| 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) | 07 Jan 2021 15:10:52 |
| User entered empty. | System | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Severity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| Query 'Consider grade 5 since subject has passed.' canceled (Site from CRA). | (b) (4), (b) (6) | 18 Mar 2021 14:57:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 10 Mar 2021 17:09:40 |
| User opened query 'Consider grade 5 since subject has passed.' (Site from CRA). | (b) (4), (b) (6) | 10 Mar 2021 17:09:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 31 Dec 2020 20:24:12 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 31 Dec 2020 20:24:12 |
| User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 20:24:12 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 31 Dec 2020 19:59:34 |
| User entered empty. | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |



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**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Is the adverse event serious?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered 'Yes (Y)' | Brianne Okunji (b) (4)<br>(b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| User closed query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety). | (b) (4), (b) (6) | 17 Feb 2021 16:40:06 |
| User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' (Site from Safety). | (b) (4), (b) (6) | 17 Feb 2021 16:40:02 |
| Query 'PV Query: Please provide/confirm the cause of death.' answered with 'Covid-19 Infection' (Site from Safety). | Nick Bart (b) (4) | 16 Feb 2021 20:11:44 |
| Query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' answered with 'Not available' (Site from Safety). | Mimi Van Der Leden (b) (4) | 16 Feb 2021 16:49:26 |
| User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety). | (b) (4), (b) (6) | 16 Feb 2021 13:54:29 |
| User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' (Site from Safety). | (b) (4), (b) (6) | 16 Feb 2021 13:54:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Feb 2021 18:00:10 |
| DataPoint Un-verified. | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:08:35 |
| User entered '1' reason for change: New Information | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:08:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered '0' | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |



FDA-CBER-2022-1614-3798235

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered '0' | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | (b) (4), (b) (6) | 30 Jan 2021 08:42:05 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Admission date updated. Discharge date and admitted to ICU still Unknown at this time' (Site from System). | Nick Bart (b) (4) | 28 Jan 2021 17:44:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | System | 31 Dec 2020 19:59:34 |
| User entered '1' | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Hospital Admission Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered '24 Dec 2020' | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Hospital Discharge Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 17:09:11 |
| User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety). | (b) (4), (b) (6) | 09 Feb 2021 18:49:55 |
| Query 'PV Query: Please provide the hospital discharge date when available. ' answered with '30Jan2021' (Site from Safety). | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:38:16 |
| DataPoint Un-verified. | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:08:35 |
| User entered '30 Jan 2021' reason for change: New Information | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:08:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety). | (b) (4), (b) (6) | 07 Jan 2021 15:11:45 |
| User entered empty. | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Admitted to ICU?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 17:09:13 |
| User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). | System | 08 Feb 2021 15:08:35 |
| Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System). | System | 08 Feb 2021 15:08:35 |
| DataPoint Un-verified. | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:08:35 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:08:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). | System | 31 Dec 2020 19:59:34 |
| User entered 'Unknown (UNK)' | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |



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**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Number of Days in ICU

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 17:12:03 |
| User closed query 'PER CDM: Re-Query: As per previous response it was reported as ‘pending medical records’. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 18 Feb 2021 11:29:49 |
| Query 'PER CDM: Re-Query: As per previous response it was reported as ‘pending medical records’. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' answered with 'medical records received and SAE updated' (Site from DM). | Mimi Van Der Leden (b) (4) | 16 Feb 2021 16:55:00 |
| DataPoint Un-verified. | Mimi Van Der Leden (b) (4) | 16 Feb 2021 16:52:56 |
| User entered '17' reason for change: New Information | Mimi Van Der Leden (b) (4) | 16 Feb 2021 16:52:56 |
| User opened query 'PER CDM: Re-Query: As per previous response it was reported as ‘pending medical records’. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 09 Feb 2021 09:06:45 |
| User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System). | (b) (4), (b) (6) | 09 Feb 2021 09:06:37 |
| Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'pending medical records' (Site from System). | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:38:30 |
| User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System). | System | 08 Feb 2021 15:08:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered empty. | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered '0' | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered '0' | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered '0' | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Relationship to investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 31 Dec 2020 20:24:12 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 31 Dec 2020 20:24:12 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 20:24:12 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 31 Dec 2020 19:59:34 |
| User entered empty. | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Relationship to Study Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 31 Dec 2020 20:24:12 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 31 Dec 2020 20:24:12 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 20:24:12 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 31 Dec 2020 19:59:34 |
| User entered empty. | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |



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**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Action taken with investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 31 Dec 2020 20:24:12 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 31 Dec 2020 20:24:12 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 20:24:12 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 31 Dec 2020 19:59:34 |
| User entered empty. | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
None

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 08 Feb 2021 15:08:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 31 Dec 2020 20:24:12 |
| User entered '0' | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Concomitant Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:56:20 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| User closed query 'Per DM CLR: Please review if ConMed should be added as there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 05 Apr 2021 07:58:00 |
| Query 'Per DM CLR: Please review if ConMed should be added as there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'updated' (Site from DM). | Nick Bart (b) (4) | 02 Apr 2021 18:31:55 |
| DataPoint Un-verified. | Nick Bart (b) (4) | 02 Apr 2021 18:31:51 |
| User entered '1' reason for change: Data Entry Error | Nick Bart (b) (4) | 02 Apr 2021 18:31:51 |
| User opened query 'Per DM CLR: Please review if ConMed should be added as there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM). | (b) (4), (b) (6) | 12 Mar 2021 08:21:35 |
| 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) (6) | 17 Feb 2021 16:40:14 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Concomitant Medication

| Audit | User | Time (GMT) |
|---|---|---|
| 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 '5 dy course of remdesivir and 10 dy course of dexamethasone for covid.' (Site from Safety). | Mimi Van Der Leden (b) (4) | 16 Feb 2021 16:51:27 |
| 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) | 16 Feb 2021 13:55:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered '0' reason for change: Data Entry Error | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 20:24:12 |
| User entered '1' | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Concomitant Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:56:22 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| User closed query 'Per CDM: Concomitant procedure response is marked. However there is no corresponding concomitant Procedure. Please review and update accordingly or else clarify.' (Site from DM). | (b) (4), (b) (6) | 05 Apr 2021 07:58:03 |
| Query 'Per CDM: Concomitant procedure response is marked. However there is no corresponding concomitant Procedure. Please review and update accordingly or else clarify.' answered with 'updated' (Site from DM). | Nick Bart (b) (4) | 02 Apr 2021 18:43:05 |
| User entered '1' reason for change: New Information | Nick Bart (b) (4) | 02 Apr 2021 18:43:00 |
| DataPoint Un-verified. | Nick Bart (b) (4) | 02 Apr 2021 18:36:54 |
| User entered '0' reason for change: New Information | Nick Bart (b) (4) | 02 Apr 2021 18:36:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 17:10:02 |
| User opened query 'Per CDM: Concomitant procedure response is marked. However there is no corresponding concomitant Procedure. Please review and update accordingly or else clarify.' (Site from DM). | (b) (4), (b) (6) | 24 Feb 2021 08:47:50 |
| DataPoint Un-verified. | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:08:35 |
| User entered '1' reason for change: New Information | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:08:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered '0' reason for change: Data Entry Error | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 20:24:12 |
| User entered '1' | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Outcome

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:10:05 |
| User closed query 'PV Query: As the subject expired, please update outcome from not resolved to fatal.' (Site from Safety). | (b) (4), (b) (6) | 17 Feb 2021 16:40:20 |
| Query 'PV Query: As the subject expired, please update outcome from not resolved to fatal.' answered with 'done' (Site from Safety). | Mimi Van Der Leden<br>(b) (4) | 16 Feb 2021 16:51:41 |
| DataPoint Un-verified. | Mimi Van Der Leden<br>(b) (4) | 16 Feb 2021 16:37:46 |
| User entered 'Fatal (FATAL)' reason for change: Data Entry Error | Mimi Van Der Leden<br>(b) (4) | 16 Feb 2021 16:37:46 |
| User opened query 'PV Query: As the subject expired, please update outcome from not resolved to fatal.' (Site from Safety). | (b) (4), (b) (6) | 16 Feb 2021 13:53:28 |
| 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) | 09 Feb 2021 18:49:58 |
| 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 'subject expired' (Site from Safety). | Mimi Van Der Leden<br>(b) (4) | 08 Feb 2021 15:38:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| 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) | 07 Jan 2021 15:09:49 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Brianne Okunji (b) (4)<br>(b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User entered empty. | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:56:33 |
| User closed query 'Please add ultra sound and blood transfusion to the narrative.' (Site from CRA). | (b) (4), (b) (6) | 14 Apr 2021 16:56:31 |
| Signature has been broken. | Nick Bart (b) (4) | 08 Apr 2021 18:16:19 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| User entered 'PATIENT WAS ADMITTED TO THE HOSPITAL ON 24DEC2020 WITH SYMPTOMS OF LOSS OF SMELL, FEVER, RUNNY NOSE. TREATED WITH STEROIDS. SUBJECT GIVEN SUPPLEMENTAL OXYGEN.<br /><br />PRELIMINARY REVIEW OF MEDICAL RECORD INDICATES COVID + ARDS WITH DECLINING RESPIRATORY STATUS. SUBJECT WAS INTUBATED AND EXPIRED ON 30JAN2021. DISCHARGE/DEATH SUMMARY HAS BEEN REQUESTED. FURTHER DETAIL WILL BE PROVIDED UPON RECEIPT OF SUCH.<br /><br />MEDICAL RECORDS REVIEWED. SUBJECT PRESENTED TO ER ON 24DEC2020 WITH COUGH, SHORTNESS OF BREATH AND FEVER. WITH SHORTNESS OF BREATH HE WAS ALSO EXPERIENCING SOME CHEST PAIN. HE WAS HYPOXIC (89% OXYGEN SATURATION) WITH A HR OF 108 AND RR OF 24. HE REQUIRED 2 L OF NASAL CANNULA TO MAINTAIN ADEQUATE OXYGENATION. HE WAS GIVEN TYLENOL FOR FEVER, AND DEXAMETHASONE WAS STARTED AS COVID WAS SUSPECTED. CHEST XRAY AND CT WERE CONSISTENT WITH COVID. HE HAD A NEGATIVE CARDIAC WORK UP FOR HIS CHEST PAIN (NEGATIVE TROPONIN AND NO ISCHEMIA ON EKG).<br /><br />TESTING FOR CORONAVIRUS ON 24DEC2021 WAS POSITIVE. NEGATIVE TEST RESULTS FOR INFLUENZA A/B AND RSV.<br /><br />OVER THE COURSE OF HOSPITALIZATION SUBJECT NEEDED UP TO 15L/MIN OXYGEN VIA NRB. HE COMPLETED A 5 DAY COURSE OF REMDESIVIR AND A 10 DAY COURSE OF DEXAMETHASONE. WITH WORSENING SHORTNESS OF BREATH AND TACHYPNEA TO 40S AND WORSENING CHEST XRAY, INFECTIOUS DISEASE BEGAN VANCOMYCIN 750MG IV Q12H AND ZOSYN 4.5 G IV Q6H FOR | Nick Bart (b) (4) | 08 Apr 2021 18:16:19 |



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**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| NEW SEPSIS OF HOSPITAL ACQUIRED PNEUMONIA. HE WAS TRIAGED TO THE SICU ON 13JAN2021 FOR ACUTE HYPOXIC RESPIRATORY INSUFFICIENCY REQUIRING HFNC 60L, 100%. <br /><br />HOSPITAL COURSE WAS COMPLICATED BY C DIFF. SUBJECT RECEIVED VANCOMYCIN.<br /><br />SUBJECT INTUBATED ON 19JAN2021. 27JAN2021, BRONCHOSCOPY PERFORMED EMERGENTLY FOR POTENTIAL AIRWAY OCCLUSION. HOWEVER AIRWAYS WERE FOUND TO BE PATENT.<br /><br />PALLIATIVE CARE WAS CONSULTED ON 26JAN2021. <br />PATIENT EXPIRED ON 30JAN2021 AT 0207.<br /><br />Subject also received blood transfusion on 28Jan2021 and CT angiography pulmonary on 05Jan2021.' reason for change: Data Entry Error | | |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| User closed query 'PV Query: Thank you for confirming autopsy results were not available. Please confirm if an autopsy was in fact performed, if known.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 05 Apr 2021 16:19:02 |
| Query 'Please add ultra sound and blood transfusion to the narrative.' answered with 'Subject did not have a blood transfusion. Did not have ultrasound' (Site from CRA). | Nick Bart (b) (4) | 02 Apr 2021 18:36:00 |
| Query 'PV Query: Thank you for confirming autopsy results were not available. Please confirm if an autopsy was in fact performed, if known.' answered with 'Highly unlikely that an autopsy was performed' (Site from Safety). | Nick Bart (b) (4) | 02 Apr 2021 18:32:24 |
| User opened query 'Please add ultra sound and blood transfusion to the narrative.' (Site from CRA). | (b) (4), (b) (6) | 10 Mar 2021 19:22:49 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 10 Mar 2021 19:22:28 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 18:55:31 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| User opened query 'PV Query: Thank you for confirming autopsy results were not available. Please confirm if an autopsy was in fact performed, if known.' (Site from Safety). | (b) (4), (b) (6) | 26 Feb 2021 13:59:45 |
| User closed query 'Per progress note on 31Dec20, subject was given supplemental oxygen. Please include in the summary when you have a moment.' (Site from CRA). | (b) (4), (b) (6) | 25 Feb 2021 07:17:48 |
| User closed query 'Per DM CLR: Narrative = TREATED WITH STEROIDS. 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) | 19 Feb 2021 10:28:22 |
| User closed query 'Per DM CLR: Narrative = SUBJECT GIVEN SUPPLEMENTAL OXYGEN. 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) | 19 Feb 2021 10:28:15 |
| User closed query 'PV Query: As case narrative was updated to reflect ICU admission, please provide dates of such. If not, please update this to no.' (Site from Safety). | (b) (4), (b) (6) | 17 Feb 2021 16:40:24 |
| Query 'PV Query: As case narrative was updated to reflect ICU admission, please provide dates of such. If not, please update this to no.' answered with 'admitted to SICU on 13Jan2021' (Site from Safety). | Mimi Van Der Leden (b) (4) | 16 Feb 2021 16:52:30 |
| Query 'Per DM CLR: Narrative = SUBJECT GIVEN SUPPLEMENTAL OXYGEN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'will be captured in conmeds' (Site from DM). | Mimi Van Der Leden (b) (4) | 16 Feb 2021 16:52:07 |
| Query 'Per DM CLR: Narrative = TREATED WITH STEROIDS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'this will be captured' (Site from DM). | Mimi Van Der Leden (b) (4) | 16 Feb 2021 16:51:54 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| User entered 'PATIENT WAS ADMITTED TO THE HOSPITAL ON 24DEC2020 WITH SYMPTOMS OF LOSS OF SMELL, FEVER, AND RUNNY NOSE. HE HAS BEEN TREATED WITH STEROIDS. HE REMAINS HOSPITALIZED. FURTHER INFORMATION WILL BE PROVIDED UPON RECEIPT OF MEDICAL RECORDS. SUBJECT GIVEN SUPPLEMENTAL OXYGEN.<br /><br />PRELIMINARY REVIEW OF MEDICAL RECORD INDICATES COVID + ARDS WITH DECLINING RESPIRATORY STATUS. SUBJECT WAS INTUBATED AND EXPIRED ON 30JAN2021. DISCHARGE/DEATH SUMMARY HAS BEEN REQUESTED. FURTHER DETAIL WILL BE PROVIDED UPON RECEIPT OF SUCH.<br /><br />Medical records reviewed. Subject presented to ER on 24Dec2020 with cough, shortness of breath and fever. With shortness of breath he was also experiencing some chest pain. He was hypoxic (89% Oxygen saturation) with a HR of 108 and RR of 24. He required 2 L of nasal cannula to maintain adequate oxygenation. He was given tylenol for fever, and dexamethasone was started as COVID was suspected. Chest xray and CT were consistent with COVID. He had a negative cardiac work up for his chest pain (negative troponin and no ischemia on EKG).<br /><br />Testing for coronavirus on 24Dec2021 was Positive. Negative test results for influenza A/B and RSV.<br /><br />Over the course of hospitalization subject needed up to 15L/min oxygen via NRB. He completed a 5 day course of remdesivir and a 10 day course of dexamethasone. With worsening shortness of breath and tachypnea to 40s and worsening chest xray, infectious disease began vancomycin 750mg IV q12h and zosyn 4.5 g IV q6h for new sepsis of hospital acquired pneumonia. He was triaged to the SICU on 13Jan2021 for acute hypoxic respiratory insufficiency requiring HFNC 60L, 100%. <br /><br />Hospital course was complicated by C difficile for which subject received po vancomycin.<br /><br | Mimi Van Der Leden (b) (4) | 16 Feb 2021 16:37:46 |



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**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| />Subject was intubated on 19Jan2021. On 27Jan2021, bronchoscopy was performed emergently for potential airway occlusion. However airways were found to be patent.<br /><br />Palliative care was consulted on 26Jan2021. <br />Patient expired on 30Jan2021 at 0207.' reason for change: Data Entry Error | | |
| User opened query 'PV Query: As case narrative was updated to reflect ICU admission, please provide dates of such. If not, please update this to no.' (Site from Safety). | (b) (4), (b) (6) | 16 Feb 2021 13:54:47 |
| Query 'PV Query: Please provide/confirm the cause of death.' canceled (Site from Safety). | (b) (4), (b) (6) | 16 Feb 2021 13:54:15 |
| User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety). | (b) (4), (b) (6) | 16 Feb 2021 13:53:44 |
| User opened query 'Per DM CLR: Narrative = SUBJECT GIVEN SUPPLEMENTAL OXYGEN. 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) | 12 Feb 2021 13:31:01 |
| User opened query 'Per DM CLR: Narrative = TREATED WITH STEROIDS. 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) | 12 Feb 2021 13:30:56 |
| User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) | 09 Feb 2021 18:50:05 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety). | (b) (4), (b) (6) | 09 Feb 2021 18:50:02 |
| User closed query 'PV Query: Did the subject have any known exposure to Covid-19? ' (Site from Safety). | (b) (4), (b) (6) | 09 Feb 2021 18:49:59 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| User entered 'PATIENT WAS ADMITTED TO THE HOSPITAL ON 24DEC2020 WITH SYMPTOMS OF LOSS OF SMELL, FEVER, AND RUNNY NOSE. HE HAS BEEN TREATED WITH STEROIDS. HE REMAINS HOSPITALIZED. FURTHER INFORMATION WILL BE PROVIDED UPON RECEIPT OF MEDICAL RECORDS. SUBJECT GIVEN SUPPLEMENTAL OXYGEN.<br /><br />Preliminary review of medical record indicates Covid + ARDS with declining respiratory status. Subject was intubated and expired on 30Jan2021. Discharge/death summary has been requested. Further detail will be provided upon receipt of such.' reason for change: Data Entry Error | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:42:37 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'pending medical record review' (Site from Safety). | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:40:01 |
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'have requested discharge summary' (Site from Safety). | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:39:47 |
| Query 'PV Query: Did the subject have any known exposure to Covid-19? ' answered with 'not known' (Site from Safety). | Mimi Van Der Leden (b) (4) | 08 Feb 2021 15:39:10 |
| User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety). | (b) (4), (b) (6) | 29 Jan 2021 19:41:39 |
| Query 'Per progress note on 31Dec20, subject was given supplemental oxygen. Please include in the summary when you have a moment.' answered with 'updated' (Site from CRA). | Nick Bart (b) (4) | 28 Jan 2021 17:42:47 |



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**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' answered with 'completed' (Site from Safety). | Nick Bart (b) (4) | 28 Jan 2021 17:42:17 |
| User entered 'PATIENT WAS ADMITTED TO THE HOSPITAL ON 24DEC2020 WITH SYMPTOMS OF LOSS OF SMELL, FEVER, AND RUNNY NOSE. HE HAS BEEN TREATED WITH STEROIDS. HE REMAINS HOSPITALIZED. FURTHER INFORMATION WILL BE PROVIDED UPON RECEIPT OF MEDICAL RECORDS. Subject given supplemental oxygen.' reason for change: Data Entry Error | Nick Bart (b) (4) | 07 Jan 2021 15:40:11 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:36:36 |
| User opened query 'Per progress note on 31Dec20, subject was given supplemental oxygen. Please include in the summary when you have a moment.' (Site from CRA). | (b) (4), (b) (6) | 07 Jan 2021 15:36:32 |
| User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety). | (b) (4), (b) (6) | 07 Jan 2021 15:12:02 |
| User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) | 07 Jan 2021 15:11:16 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety). | (b) (4), (b) (6) | 07 Jan 2021 15:10:22 |
| User opened query 'PV Query: Did the subject have any known exposure to Covid-19? ' (Site from Safety). | (b) (4), (b) (6) | 07 Jan 2021 15:08:43 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | System | 31 Dec 2020 20:24:12 |
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System). | System | 31 Dec 2020 20:24:12 |
| User entered 'Patient was admitted to the hospital on 24DEC2020 with symptoms of loss of smell, fever, and runny nose. He has been treated with steroids. He remains hospitalized. Further information will be provided upon receipt of medical records.' reason for change: Data Entry Error | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 20:24:12 |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | System | 31 Dec 2020 19:59:34 |
| User entered empty. | Brianne Okunji (b) (4) (b) (4) | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Serious Adverse Event Derived (CSA Programming Field Ony)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User entered '1' | System | 31 Dec 2020 19:59:34 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User entered '1' | System | 31 Dec 2020 19:59:34 |



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**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (1)**
**Generated On: 10 Jun 2021 10:28:25**
Admitted to ICU Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:19:53 |
| User entered '1' | System | 08 Feb 2021 15:08:35 |
| User entered '0' | System | 31 Dec 2020 19:59:34 |



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**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
AEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |



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**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Adverse event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Clostridia infections, PT: Clostridium difficile infection, LLT: Clostridium difficile infection - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 16 Feb 2021 20:15:01 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 16 Feb 2021 20:15:01 |
| Data point term sent to Coder | System | 16 Feb 2021 20:14:05 |
| User entered 'Clostridium difficile' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Was this a medically-attended AE?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |



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**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Was this a Solicited Adverse Reaction?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Is this event a confirmed diagnosis of Symptomatic Covid-19?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '03 Jan 2021' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |



FDA-CBER-2022-1614-3798271

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Start time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
AE start date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User entered empty. | System | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |



FDA-CBER-2022-1614-3798274

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, end date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:57:23 |
| User closed query 'MAR does not list end date for C. Diff.' (Site from CRA). | (b) (4), (b) (6) | 14 Apr 2021 16:57:21 |
| Query 'MAR does not list end date for C. Diff.' answered with 'diarrhea and medications ended on 17 JAN 2021. Correct as entered per PI.' (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 21:47:59 |
| User opened query 'MAR does not list end date for C. Diff.' (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 15:50:05 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Apr 2021 15:49:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 15:49:05 |
| User closed query 'Per Consultation note (page 5), subject still had C Diff. Please confirm and reconcile.' (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 15:49:03 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| Query 'Per Consultation note (page 5), subject still had C Diff. Please confirm and reconcile.' answered with 'per consultation note: "He has also had C. Diff. colitis this stay and is on oral vancomycin with diarrhea resolved. Vancomycin ended 17Jan2021."' (Site from CRA). | Nick Bart (b) (4) | 02 Apr 2021 18:46:13 |
| User opened query 'Per Consultation note (page 5), subject still had C Diff. Please confirm and reconcile.' (Site from CRA). | (b) (4), (b) (6) | 10 Mar 2021 19:04:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 10 Mar 2021 18:55:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '17 Jan 2021' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
End time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
AE End Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User entered empty. | System | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Severity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Is the adverse event serious?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |



FDA-CBER-2022-1614-3798282

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Hospital Admission Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |



FDA-CBER-2022-1614-3798283

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Hospital Discharge Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |



FDA-CBER-2022-1614-3798284

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Admitted to ICU?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Number of Days in ICU

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |



FDA-CBER-2022-1614-3798286

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |



FDA-CBER-2022-1614-3798289

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Relationship to investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'Not Related (NOT RELATED)' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Relationship to Study Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'Not Related (NOT RELATED)' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |



FDA-CBER-2022-1614-3798291

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Action taken with investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
None

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Concomitant Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '1' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Concomitant Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Outcome

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:13:45 |



FDA-CBER-2022-1614-3798298

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Serious Adverse Event Derived (CSA Programming Field Ony)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User entered '0' | System | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |
| User entered '0' | System | 16 Feb 2021 20:13:45 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (2)**
**Generated On: 10 Jun 2021 10:28:25**
Admitted to ICU Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:05:00 |



FDA-CBER-2022-1614-3798301

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
AEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |



FDA-CBER-2022-1614-3798302

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Adverse event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Hospital acquired pneumonia - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 16 Feb 2021 20:16:01 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 16 Feb 2021 20:16:01 |
| Data point term sent to Coder | System | 16 Feb 2021 20:15:06 |
| User entered 'hospital acquired pneumonia' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Was this a medically-attended AE?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Was this a Solicited Adverse Reaction?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Is this event a confirmed diagnosis of Symptomatic Covid-19?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '13 Jan 2021' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |



FDA-CBER-2022-1614-3798307

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Start time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
AE start date and time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User entered empty. | System | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, end date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 21:38:37 |
| User closed query 'Per consultation note on 27Jan21, subject had continued Pnuemonia. Please reconcile and confirm.' (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 21:38:33 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| Query 'Per consultation note on 27Jan21, subject had continued Pnuemonia. Please reconcile and confirm.' answered with 'Vancomycin and Zosyn were given for Hospital Acquired Pneumonia. Both medications were discontinued on 22Jan2021.' (Site from CRA). | Nick Bart (b) (4) | 02 Apr 2021 18:47:32 |
| User opened query 'Per consultation note on 27Jan21, subject had continued Pnuemonia. Please reconcile and confirm.' (Site from CRA). | (b) (4), (b) (6) | 10 Mar 2021 19:21:43 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 10 Mar 2021 19:21:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '22 Jan 2021' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |



FDA-CBER-2022-1614-3798311

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
End time *(00:00-23:59)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
AE End Date and Time (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User entered empty. | System | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Severity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Is the adverse event serious?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |



FDA-CBER-2022-1614-3798315

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |



FDA-CBER-2022-1614-3798317

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Hospital Admission Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |



FDA-CBER-2022-1614-3798319

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Hospital Discharge Date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |



FDA-CBER-2022-1614-3798320

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Admitted to ICU?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Number of Days in ICU

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Relationship to investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'Not Related (NOT RELATED)' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Relationship to Study Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'Not Related (NOT RELATED)' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Action taken with investigational product

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
None

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Concomitant Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '1' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Concomitant Procedure

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Outcome

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Narrative

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User signature succeeded. | Mimi Van Der Leden | 07 Apr 2021 21:21:58 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 18:55:31 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:14:47 |



FDA-CBER-2022-1614-3798334

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Serious Adverse Event Derived (CSA Programming Field Ony)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User entered '0' | System | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |
| User entered '0' | System | 16 Feb 2021 20:14:47 |

**US3952094**
**Folder: Adverse Events**
**Form: Adverse Events (3)**
**Generated On: 10 Jun 2021 10:28:25**
Admitted to ICU Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:04:41 |



FDA-CBER-2022-1614-3798337

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination Summary**
**Generated On: 10 Jun 2021 10:28:25**
Were any prior/concomitant medications and/or vaccinations taken?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 17:43:41 |
| User closed query 'Please add con procedures from hospitalization.' (Site from CRA). | (b) (4), (b) (6) | 14 Apr 2021 17:43:29 |
| Query 'Please add con procedures from hospitalization.' answered with 'updated' (Site from CRA). | Nick Bart (b) (4) | 08 Apr 2021 18:28:40 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 10 Mar 2021 19:23:30 |
| User opened query 'Please add con procedures from hospitalization.' (Site from CRA). | (b) (4), (b) (6) | 10 Mar 2021 17:51:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:53:04 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:29:34 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 15:31:38 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 15:31:38 |
| Data point term sent to Coder | System | 28 Sep 2020 15:30:47 |
| User entered 'lisinopril' | Nick Bart (b) (4) | 28 Sep 2020 15:29:55 |



FDA-CBER-2022-1614-3798339

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:29:55 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'hypertension' | Nick Bart (b) (4) | 28 Sep 2020 15:29:55 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered '20' | Nick Bart (b) (4) | 28 Sep 2020 15:29:55 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'mg (mg)' | Nick Bart (b) (4) | 28 Sep 2020 15:29:55 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:29:55 |



FDA-CBER-2022-1614-3798344

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'once daily (QD)' | Nick Bart (b) (4) | 28 Sep 2020 15:29:55 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:29:55 |



FDA-CBER-2022-1614-3798346

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Oral (ORAL)' | Nick Bart (b) (4) | 28 Sep 2020 15:29:55 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:29:55 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'un UNK 2010' | Nick Bart (b) (4) | 28 Sep 2020 15:29:55 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:29:55 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:29:55 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:29:55 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:29:55 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 28 Sep 2020 15:29:55 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 28 Sep 2020 15:29:55 |



FDA-CBER-2022-1614-3798355

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (1)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '804 (804)' | System | 28 Sep 2020 15:29:55 |



FDA-CBER-2022-1614-3798356

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: METFORMIN HYDROCHLORIDE;SITAGLIPTIN, PRODUCTSYNONYM: JANUMET [METFORMIN HYDROCHLORIDE;SITAGLIPTIN] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 15:31:37 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 15:31:37 |
| Data point term sent to Coder | System | 28 Sep 2020 15:30:48 |
| User entered 'janumet' | Nick Bart (b) (4) | 28 Sep 2020 15:30:23 |



FDA-CBER-2022-1614-3798357

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:30:23 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'diabetes' | Nick Bart (b) (4) | 28 Sep 2020 15:30:23 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered '50/1000' | Nick Bart (b) (4) | 28 Sep 2020 15:30:23 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'mg (mg)' | Nick Bart (b) (4) | 28 Sep 2020 15:30:23 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:30:23 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'twice daily (BID)' | Nick Bart (b) (4) | 28 Sep 2020 15:30:23 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:30:23 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Oral (ORAL)' | Nick Bart (b) (4) | 28 Sep 2020 15:30:23 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:30:23 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'un UNK 2019' | Nick Bart (b) (4) | 28 Sep 2020 15:30:23 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:30:23 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:30:23 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:30:23 |



FDA-CBER-2022-1614-3798370

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:30:23 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '2' | System | 28 Sep 2020 15:30:23 |



FDA-CBER-2022-1614-3798372

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 28 Sep 2020 15:30:23 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (2)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '804 (804)' | System | 28 Sep 2020 15:30:23 |



FDA-CBER-2022-1614-3798374

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 15:32:40 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 15:32:40 |
| Data point term sent to Coder | System | 28 Sep 2020 15:31:52 |
| User entered 'simvastatin' | Nick Bart (b) (4) | 28 Sep 2020 15:30:51 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:30:51 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'high cholesterol' | Nick Bart (b) (4) | 28 Sep 2020 15:30:51 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered '20' | Nick Bart (b) (4) | 28 Sep 2020 15:30:51 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'mg (mg)' | Nick Bart (b) (4) | 28 Sep 2020 15:30:51 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:30:51 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'once daily (QD)' | Nick Bart (b) (4) | 28 Sep 2020 15:30:51 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:30:51 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Oral (ORAL)' | Nick Bart (b) (4) | 28 Sep 2020 15:30:51 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:30:51 |



FDA-CBER-2022-1614-3798384

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'un UNK 2015' | Nick Bart (b) (4) | 28 Sep 2020 15:30:51 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:30:51 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:30:51 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:30:51 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:30:51 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 28 Sep 2020 15:30:51 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 28 Sep 2020 15:30:51 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (3)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '804 (804)' | System | 28 Sep 2020 15:30:51 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 15:32:40 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 15:32:40 |
| Data point term sent to Coder | System | 28 Sep 2020 15:31:52 |
| User entered 'meloxicam' | Nick Bart (b) (4) | 28 Sep 2020 15:31:22 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:31:22 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'left knee pain' | Nick Bart (b) (4) | 28 Sep 2020 15:31:22 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered '7.5' | Nick Bart (b) (4) | 28 Sep 2020 15:31:22 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'mg (mg)' | Nick Bart (b) (4) | 28 Sep 2020 15:31:22 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:31:22 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'once daily (QD)' | Nick Bart (b) (4) | 28 Sep 2020 15:31:22 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:31:22 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Oral (ORAL)' | Nick Bart (b) (4) | 28 Sep 2020 15:31:22 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:31:22 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'un Mar 2020' | Nick Bart (b) (4) | 28 Sep 2020 15:31:22 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:31:22 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:31:22 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:31:22 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:31:22 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 28 Sep 2020 15:31:22 |



FDA-CBER-2022-1614-3798408

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 28 Sep 2020 15:31:22 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (4)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '804 (804)' | System | 28 Sep 2020 15:31:22 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 15:33:44 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Sep 2020 15:33:44 |
| Data point term sent to Coder | System | 28 Sep 2020 15:32:53 |
| User entered 'influenza vaccine' | Nick Bart (b) (4) | 28 Sep 2020 15:31:52 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Yes (Y)' | Nick Bart (b) (4) | 28 Sep 2020 15:31:52 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'flu prevention' | Nick Bart (b) (4) | 28 Sep 2020 15:31:52 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered '0.5' | Nick Bart (b) (4) | 28 Sep 2020 15:31:52 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'mL (mL)' | Nick Bart (b) (4) | 28 Sep 2020 15:31:52 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:31:52 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'once daily (QD)' | Nick Bart (b) (4) | 28 Sep 2020 15:31:52 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:31:52 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | Nick Bart (b) (4) | 28 Sep 2020 15:31:52 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 28 Sep 2020 15:31:52 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered '23 Aug 2020' | Nick Bart (b) (4) | 28 Sep 2020 15:31:52 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered '0' | Nick Bart (b) (4) | 28 Sep 2020 15:31:52 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:31:52 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered '23 Aug 2020' | Nick Bart (b) (4) | 28 Sep 2020 15:31:52 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'No (N)' | Nick Bart (b) (4) | 28 Sep 2020 15:31:52 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 28 Sep 2020 15:31:52 |



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**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 28 Sep 2020 15:31:52 |



FDA-CBER-2022-1614-3798427

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (5)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '804 (804)' | System | 28 Sep 2020 15:31:52 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: HYDROCORTISONE, PRODUCTSYNONYM: CORTISONE [HYDROCORTISONE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 04 Nov 2020 20:35:33 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 04 Nov 2020 20:35:33 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: CORTISONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Oct 2020 10:10:26 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Oct 2020 10:10:26 |
| Data point term sent to Coder | System | 14 Oct 2020 20:31:16 |
| User entered 'cortisone injection' | Nick Bart (b) (4) | 14 Oct 2020 20:31:14 |



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**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'No (N)' | Nick Bart (b) (4) | 14 Oct 2020 20:31:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening LEFT KNEE PAIN should be recorded, and update con med indication or provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 28 Dec 2020 07:16:15 |
| Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening LEFT KNEE PAIN should be recorded, and update con med indication or provide clarification. ' answered with 'Not added as a result of worsening condition' (Site from DM). | Nick Bart (b) (4) | 22 Dec 2020 15:17:03 |
| User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening LEFT KNEE PAIN should be recorded, and update con med indication or provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 27 Nov 2020 15:42:28 |
| User entered 'left knee pain' | Nick Bart (b) (4) | 14 Oct 2020 20:31:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered '1' | Nick Bart (b) (4) | 14 Oct 2020 20:31:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Other (OTHER)' | Nick Bart (b) (4) | 14 Oct 2020 20:31:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'injection' | Nick Bart (b) (4) | 14 Oct 2020 20:31:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'once (ONCE)' | Nick Bart (b) (4) | 14 Oct 2020 20:31:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Nick Bart (b) (4) | 14 Oct 2020 20:31:14 |



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**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Other (OTHER)' | Nick Bart (b) (4) | 14 Oct 2020 20:31:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'intra-articular' | Nick Bart (b) (4) | 14 Oct 2020 20:31:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered '09 Oct 2020' | Nick Bart (b) (4) | 14 Oct 2020 20:31:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered '0' | Nick Bart (b) (4) | 14 Oct 2020 20:31:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'No (N)' | Nick Bart (b) (4) | 14 Oct 2020 20:31:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered '09 Oct 2020' | Nick Bart (b) (4) | 14 Oct 2020 20:31:14 |



FDA-CBER-2022-1614-3798442

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'No (N)' | Nick Bart (b) (4) | 14 Oct 2020 20:31:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 14 Oct 2020 20:31:14 |



FDA-CBER-2022-1614-3798444

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 14 Oct 2020 20:31:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (6)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 14 Oct 2020 20:31:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:27:49 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 12 Mar 2021 07:51:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 12 Mar 2021 07:51:40 |
| Data point term sent to Coder | System | 16 Feb 2021 20:18:08 |
| User entered 'Remdesivir' | Nick Bart (b) (4) | 16 Feb 2021 20:17:14 |



FDA-CBER-2022-1614-3798447

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:27:52 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:17:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:44:31 |
| User entered 'Sars-Cov-2 Infection' | Nick Bart (b) (4) | 16 Feb 2021 20:17:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:44:33 |
| User entered '100' | Nick Bart (b) (4) | 16 Feb 2021 20:17:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:44:35 |
| User entered 'mg (mg)' | Nick Bart (b) (4) | 16 Feb 2021 20:17:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:44:36 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:17:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:44:39 |
| User entered 'once daily (QD)' | Nick Bart (b) (4) | 16 Feb 2021 20:17:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:44:41 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:17:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:44:43 |
| User entered 'Intravenous (INTRAVENOUS)' | Nick Bart (b) (4) | 16 Feb 2021 20:17:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 18:44:45 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:17:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:44:48 |
| User entered '25 Dec 2020' | Nick Bart (b) (4) | 16 Feb 2021 20:17:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:44:50 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:17:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:44:51 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:17:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:44:53 |
| User entered '29 Dec 2020' | Nick Bart (b) (4) | 16 Feb 2021 20:17:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:44:55 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:17:14 |



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**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 16 Feb 2021 20:17:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 16 Feb 2021 20:17:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (7)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '804 (804)' | System | 16 Feb 2021 20:17:14 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:45:00 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Feb 2021 21:12:22 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Feb 2021 21:12:22 |
| Data point term sent to Coder | System | 16 Feb 2021 20:18:11 |
| User entered 'dexamethasone' | Nick Bart (b) (4) | 16 Feb 2021 20:18:10 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:45:02 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:18:10 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:45:05 |
| User entered 'Sars-Cov-2 Infection' | Nick Bart (b) (4) | 16 Feb 2021 20:18:10 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:45:09 |
| User entered '6' | Nick Bart (b) (4) | 16 Feb 2021 20:18:10 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:45:58 |
| User entered 'mg (mg)' | Nick Bart (b) (4) | 16 Feb 2021 20:18:10 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:46:00 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:18:10 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:46:01 |
| User entered 'once daily (QD)' | Nick Bart (b) (4) | 16 Feb 2021 20:18:10 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:46:03 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:18:10 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:46:05 |
| User entered 'Intravenous (INTRAVENOUS)' | Nick Bart (b) (4) | 16 Feb 2021 20:18:10 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 18:46:07 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:18:10 |



FDA-CBER-2022-1614-3798474

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:46:09 |
| User entered '25 Dec 2020' | Nick Bart (b) (4) | 16 Feb 2021 20:18:10 |



FDA-CBER-2022-1614-3798475

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:46:10 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:18:10 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:46:12 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:18:10 |



FDA-CBER-2022-1614-3798477

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:52:04 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 08 Apr 2021 18:46:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:46:14 |
| User entered '03 Jan 2021' | Nick Bart (b) (4) | 16 Feb 2021 20:18:10 |



FDA-CBER-2022-1614-3798478

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:46:17 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:18:10 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 16 Feb 2021 20:18:10 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 16 Feb 2021 20:18:10 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (8)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '804 (804)' | System | 16 Feb 2021 20:18:10 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:52:46 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 28 Feb 2021 17:43:28 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 28 Feb 2021 17:43:28 |
| Data point term sent to Coder | System | 16 Feb 2021 20:19:12 |
| User entered 'vancomycin' | Nick Bart (b) (4) | 16 Feb 2021 20:19:05 |



FDA-CBER-2022-1614-3798483

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:52:47 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:19:05 |



FDA-CBER-2022-1614-3798484

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:52:49 |
| User entered 'hospital acquired pneumonia' | Nick Bart (b) (4) | 16 Feb 2021 20:19:05 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:52:51 |
| User entered '750' | Nick Bart (b) (4) | 16 Feb 2021 20:19:05 |



FDA-CBER-2022-1614-3798486

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:52:53 |
| User entered 'mg (mg)' | Nick Bart (b) (4) | 16 Feb 2021 20:19:05 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:52:54 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:19:05 |



FDA-CBER-2022-1614-3798488

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:52:56 |
| User entered 'twice daily (BID)' | Nick Bart (b) (4) | 16 Feb 2021 20:19:05 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:53:03 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:19:05 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:53:05 |
| User entered 'Intravenous (INTRAVENOUS)' | Nick Bart (b) (4) | 16 Feb 2021 20:19:05 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:53:06 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:19:05 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:53:39 |
| User entered '13 Jan 2021' | Nick Bart (b) (4) | 16 Feb 2021 20:19:05 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:53:41 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:19:05 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:53:43 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:19:05 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:58:54 |
| User entered '22 Jan 2021' | Nick Bart (b) (4) | 16 Feb 2021 20:19:05 |



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**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:58:10 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:19:05 |



FDA-CBER-2022-1614-3798497

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '2' | System | 16 Feb 2021 20:19:05 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 16 Feb 2021 20:19:05 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (9)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '804 (804)' | System | 16 Feb 2021 20:19:05 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:59:04 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 16 Feb 2021 20:21:01 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 16 Feb 2021 20:21:01 |
| Data point term sent to Coder | System | 16 Feb 2021 20:20:13 |
| User entered 'zosyn' | Nick Bart (b) (4) | 16 Feb 2021 20:19:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:59:05 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:19:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:59:06 |
| User entered 'hospital acquired pneumonia' | Nick Bart (b) (4) | 16 Feb 2021 20:19:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:59:08 |
| User entered '4.5' | Nick Bart (b) (4) | 16 Feb 2021 20:19:45 |



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**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:59:10 |
| 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. ' (Site from DM). | (b) (4), (b) (6) | 05 Apr 2021 07:57:28 |
| 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. ' answered with 'updated' (Site from DM). | Nick Bart (b) (4) | 02 Apr 2021 18:54:09 |
| User entered 'g (g)' reason for change: Data Entry Error | Nick Bart (b) (4) | 02 Apr 2021 18:54:05 |
| 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. ' (Site from DM). | (b) (4), (b) (6) | 10 Mar 2021 10:15:37 |
| User entered 'mg (mg)' | Nick Bart (b) (4) | 16 Feb 2021 20:19:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:59:12 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:19:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:59:14 |
| User entered 'four times daily (QID)' | Nick Bart (b) (4) | 16 Feb 2021 20:19:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:59:16 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:19:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:59:18 |
| User entered 'Intravenous (INTRAVENOUS)' | Nick Bart (b) (4) | 16 Feb 2021 20:19:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 18:59:19 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:19:45 |



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**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:59:21 |
| User entered '13 Jan 2021' | Nick Bart (b) (4) | 16 Feb 2021 20:19:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:59:23 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:19:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:59:24 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:19:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:59:28 |
| User entered '22 Jan 2021' | Nick Bart (b) (4) | 16 Feb 2021 20:19:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:59:30 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:19:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '4' | System | 16 Feb 2021 20:19:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 16 Feb 2021 20:19:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (10)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '804 (804)' | System | 16 Feb 2021 20:19:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 19:03:55 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 16 Feb 2021 20:22:02 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 16 Feb 2021 20:22:02 |
| Data point term sent to Coder | System | 16 Feb 2021 20:21:25 |
| User entered 'vancomycin' | Nick Bart (b) (4) | 16 Feb 2021 20:21:15 |



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**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 19:03:56 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:21:15 |



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**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 19:03:58 |
| User entered 'Clostridium difficile' | Nick Bart (b) (4) | 16 Feb 2021 20:21:15 |



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**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 19:03:59 |
| User entered '125' | Nick Bart (b) (4) | 16 Feb 2021 20:21:15 |



FDA-CBER-2022-1614-3798522

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:04:01 |
| User entered 'mg (mg)' | Nick Bart (b) (4) | 16 Feb 2021 20:21:15 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 19:04:02 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:21:15 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 19:04:05 |
| User entered 'four times daily (QID)' | Nick Bart (b) (4) | 16 Feb 2021 20:21:15 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 19:04:07 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:21:15 |



FDA-CBER-2022-1614-3798526

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:04:09 |
| User entered 'Oral (ORAL)' | Nick Bart (b) (4) | 16 Feb 2021 20:21:15 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 19:04:11 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:21:15 |



FDA-CBER-2022-1614-3798528

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:19:38 |
| Query 'MAR states that this began on 3Jan21.' canceled (Site from CRA). | (b) (4), (b) (6) | 08 Apr 2021 19:19:36 |
| User opened query 'MAR states that this began on 3Jan21.' (Site from CRA). | (b) (4), (b) (6) | 08 Apr 2021 19:03:08 |
| User entered '04 Jan 2021' | Nick Bart (b) (4) | 16 Feb 2021 20:21:15 |



FDA-CBER-2022-1614-3798529

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:03:23 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:21:15 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:03:21 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:21:15 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 21:47:34 |
| User closed query 'Per 8Jan21 notes, subject was on 250 mL of Vancomycin 4x a day. Please reconcile.' (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 21:47:32 |
| Query 'Per 8Jan21 notes, subject was on 250 mL of Vancomycin 4x a day. Please reconcile.' answered with 'Correct as entered per PI.' (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 16:21:59 |
| User opened query 'Per 8Jan21 notes, subject was on 250 mL of Vancomycin 4x a day. Please reconcile.' (Site from CRA). | (b) (4), (b) (6) | 08 Apr 2021 19:03:49 |
| User entered '17 Jan 2021' | Nick Bart (b) (4) | 16 Feb 2021 20:21:15 |



FDA-CBER-2022-1614-3798532

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 19:03:51 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:21:15 |



FDA-CBER-2022-1614-3798533

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '4' | System | 16 Feb 2021 20:21:15 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 16 Feb 2021 20:21:15 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (11)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '804 (804)' | System | 16 Feb 2021 20:21:15 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 19:04:23 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 16 Feb 2021 20:23:02 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 16 Feb 2021 20:23:02 |
| Data point term sent to Coder | System | 16 Feb 2021 20:22:26 |
| User entered 'azithromycin' | Nick Bart (b) (4) | 16 Feb 2021 20:22:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:04:25 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:22:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:04:27 |
| User closed query 'Per DM CLR: For Please review corresponding AE as this does not indicate “Other Action Taken = Concomitant Medication”, please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 05 Apr 2021 07:57:16 |
| Query 'Per DM CLR: For Please review corresponding AE as this does not indicate “Other Action Taken = Concomitant Medication”, please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' answered with 'Updated' (Site from DM). | Nick Bart (b) (4) | 02 Apr 2021 18:55:41 |
| User opened query 'Per DM CLR: For Please review corresponding AE as this does not indicate “Other Action Taken = Concomitant Medication”, please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 10 Mar 2021 10:15:31 |
| User entered 'Sars-Cov-2 Infection' | Nick Bart (b) (4) | 16 Feb 2021 20:22:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 19:04:53 |
| User entered '250' | Nick Bart (b) (4) | 16 Feb 2021 20:22:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:04:54 |
| User entered 'mg (mg)' | Nick Bart (b) (4) | 16 Feb 2021 20:22:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 19:04:56 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:22:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:04:57 |
| User entered 'once daily (QD)' | Nick Bart (b) (4) | 16 Feb 2021 20:22:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:04:59 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:22:11 |



FDA-CBER-2022-1614-3798544

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:05:00 |
| User entered 'Oral (ORAL)' | Nick Bart (b) (4) | 16 Feb 2021 20:22:11 |



FDA-CBER-2022-1614-3798545

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 19:05:02 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:22:11 |



FDA-CBER-2022-1614-3798546

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:05:04 |
| User entered '25 Dec 2020' | Nick Bart (b) (4) | 16 Feb 2021 20:22:11 |



FDA-CBER-2022-1614-3798547

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:05:06 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:22:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:05:08 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:22:11 |



FDA-CBER-2022-1614-3798549

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 21:47:18 |
| User closed query 'Cannot find end date in MAR.' (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 21:47:17 |
| Query 'Cannot find end date in MAR.' answered with 'Per PI correct as entered.' (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 21:57:29 |
| User opened query 'Cannot find end date in MAR.' (Site from CRA). | (b) (4), (b) (6) | 08 Apr 2021 19:13:18 |
| User entered '29 Dec 2020' | Nick Bart (b) (4) | 16 Feb 2021 20:22:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 19:05:10 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:22:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 16 Feb 2021 20:22:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 16 Feb 2021 20:22:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (12)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '804 (804)' | System | 16 Feb 2021 20:22:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 19:13:39 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 16 Feb 2021 21:03:02 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 16 Feb 2021 21:03:02 |
| Data point term sent to Coder | System | 16 Feb 2021 20:24:28 |
| User entered 'Ceftriaxone' | Nick Bart (b) (4) | 16 Feb 2021 20:23:49 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:14:01 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:23:49 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:14:03 |
| User entered 'Sars-Cov-2 Infection' | Nick Bart (b) (4) | 16 Feb 2021 20:23:49 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:20:06 |
| User entered '1' | Nick Bart (b) (4) | 16 Feb 2021 20:23:49 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:20:07 |
| User entered 'g (g)' | Nick Bart (b) (4) | 16 Feb 2021 20:23:49 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 19:20:09 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:23:49 |



FDA-CBER-2022-1614-3798560

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:20:10 |
| User entered 'once daily (QD)' | Nick Bart (b) (4) | 16 Feb 2021 20:23:49 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 19:20:11 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:23:49 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:20:13 |
| User entered 'Intravenous (INTRAVENOUS)' | Nick Bart (b) (4) | 16 Feb 2021 20:23:49 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 19:20:15 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:23:49 |



FDA-CBER-2022-1614-3798564

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:20:17 |
| User entered '25 Dec 2020' | Nick Bart (b) (4) | 16 Feb 2021 20:23:49 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:20:18 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:23:49 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:20:21 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:23:49 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 21:46:48 |
| User closed query 'Can not find end date on MAR.' (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 21:46:46 |
| Query 'Can not find end date on MAR.' answered with 'Per PI correct as entered.' (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 21:57:39 |
| User opened query 'Can not find end date on MAR.' (Site from CRA). | (b) (4), (b) (6) | 08 Apr 2021 19:23:14 |
| User entered '25 Dec 2020' | Nick Bart (b) (4) | 16 Feb 2021 20:23:49 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 19:21:38 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:23:49 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 16 Feb 2021 20:23:49 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 16 Feb 2021 20:23:49 |



FDA-CBER-2022-1614-3798571

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (13)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '804 (804)' | System | 16 Feb 2021 20:23:49 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:31:20 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Feb 2021 21:15:03 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Feb 2021 21:15:03 |
| Data point term sent to Coder | System | 16 Feb 2021 20:25:29 |
| User entered 'Enoxaparin' | Nick Bart (b) (4) | 16 Feb 2021 20:24:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:31:22 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:24:45 |



FDA-CBER-2022-1614-3798574

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:31:25 |
| User entered 'Sars-Cov-2 Infection' | Nick Bart (b) (4) | 16 Feb 2021 20:24:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:31:27 |
| User entered '40' | Nick Bart (b) (4) | 16 Feb 2021 20:24:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:31:29 |
| User entered 'mg (mg)' | Nick Bart (b) (4) | 16 Feb 2021 20:24:45 |



FDA-CBER-2022-1614-3798577

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:31:31 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:24:45 |



FDA-CBER-2022-1614-3798578

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:31:34 |
| User entered 'once daily (QD)' | Nick Bart (b) (4) | 16 Feb 2021 20:24:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 21:45:28 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:24:45 |



FDA-CBER-2022-1614-3798580

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:31:44 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | Nick Bart (b) (4) | 16 Feb 2021 20:24:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 19:31:48 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:24:45 |



FDA-CBER-2022-1614-3798582

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:31:49 |
| User entered '25 Dec 2020' | Nick Bart (b) (4) | 16 Feb 2021 20:24:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:32:47 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:24:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:32:49 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:24:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 21:46:31 |
| User closed query 'No end date available on med records. Please reconcile.' (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 21:46:29 |
| Query 'No end date available on med records. Please reconcile.' answered with 'Per PI correct as entered.' (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 21:57:54 |
| User opened query 'No end date available on med records. Please reconcile.' (Site from CRA). | (b) (4), (b) (6) | 08 Apr 2021 19:35:33 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 08 Apr 2021 19:35:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:35:12 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 08 Apr 2021 19:35:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:34:53 |
| User entered '30 Jan 2021' | Nick Bart (b) (4) | 16 Feb 2021 20:24:45 |



FDA-CBER-2022-1614-3798586

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:32:52 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:24:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 16 Feb 2021 20:24:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 16 Feb 2021 20:24:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (14)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '804 (804)' | System | 16 Feb 2021 20:24:45 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:35:40 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Feb 2021 21:28:02 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Feb 2021 21:28:02 |
| Data point term sent to Coder | System | 16 Feb 2021 20:25:29 |
| User entered 'dexamethasone' | Nick Bart (b) (4) | 16 Feb 2021 20:25:29 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 19:35:42 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:25:29 |



FDA-CBER-2022-1614-3798592

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:35:44 |
| User entered 'Sars-Cov-2 Infection' | Nick Bart (b) (4) | 16 Feb 2021 20:25:29 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:35:46 |
| User entered '6' | Nick Bart (b) (4) | 16 Feb 2021 20:25:29 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:35:49 |
| User entered 'mg (mg)' | Nick Bart (b) (4) | 16 Feb 2021 20:25:29 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 19:35:50 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:25:29 |



FDA-CBER-2022-1614-3798596

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:35:53 |
| User entered 'once (ONCE)' | Nick Bart (b) (4) | 16 Feb 2021 20:25:29 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:35:55 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:25:29 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 19:35:57 |
| User entered 'Intravenous (INTRAVENOUS)' | Nick Bart (b) (4) | 16 Feb 2021 20:25:29 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 19:35:59 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:25:29 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:36:02 |
| User entered '25 Dec 2020' | Nick Bart (b) (4) | 16 Feb 2021 20:25:29 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:36:05 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:25:29 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:36:07 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:25:29 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:37:24 |
| User entered '25 Dec 2020' | Nick Bart (b) (4) | 16 Feb 2021 20:25:29 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:36:10 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:25:29 |



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**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 16 Feb 2021 20:25:29 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 16 Feb 2021 20:25:29 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (15)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered empty. | System | 16 Feb 2021 20:25:29 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
Name of Medication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:37:33 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 03 Mar 2021 13:47:58 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 03 Mar 2021 13:47:58 |
| Data point term sent to Coder | System | 16 Feb 2021 20:27:31 |
| User entered 'tylenol [acetaminophen]' | Nick Bart (b) (4) | 16 Feb 2021 20:27:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
Prophylaxis

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 19:37:35 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:27:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:37:37 |
| User entered 'Sars-Cov-2 Infection' | Nick Bart (b) (4) | 16 Feb 2021 20:27:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
Dose per administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:40:06 |
| User entered '1000' | Nick Bart (b) (4) | 16 Feb 2021 20:27:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
Dose unit

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:40:05 |
| User entered 'mg (mg)' | Nick Bart (b) (4) | 16 Feb 2021 20:27:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:40:03 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:27:11 |



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**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
Frequency

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:40:01 |
| User entered 'three times daily (TID)' | Nick Bart (b) (4) | 16 Feb 2021 20:27:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:39:59 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:27:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
Route of administration

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:39:58 |
| User entered 'Oral (ORAL)' | Nick Bart (b) (4) | 16 Feb 2021 20:27:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 19:39:56 |
| User entered empty. | Nick Bart (b) (4) | 16 Feb 2021 20:27:11 |



FDA-CBER-2022-1614-3798618

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
Start date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:39:54 |
| User entered '24 Dec 2020' | Nick Bart (b) (4) | 16 Feb 2021 20:27:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
Start date completely unknown

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:39:52 |
| User entered '0' | Nick Bart (b) (4) | 16 Feb 2021 20:27:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
Ongoing?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:39:50 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:27:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
If not Ongoing, End date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 21:46:18 |
| User closed query 'Can not find end date on MAR.' (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 21:46:16 |
| Query 'Can not find end date on MAR.' answered with 'Per PI correct as entered.' (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 21:58:07 |
| User opened query 'Can not find end date on MAR.' (Site from CRA). | (b) (4), (b) (6) | 08 Apr 2021 19:40:25 |
| User entered '30 Jan 2021' | Nick Bart (b) (4) | 16 Feb 2021 20:27:11 |



FDA-CBER-2022-1614-3798622

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 19:39:48 |
| User entered 'No (N)' | Nick Bart (b) (4) | 16 Feb 2021 20:27:11 |

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
Separate Dosage Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '3' | System | 16 Feb 2021 20:27:11 |



FDA-CBER-2022-1614-3798624

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Unit Number (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '1' | System | 16 Feb 2021 20:27:11 |



FDA-CBER-2022-1614-3798625

**US3952094**
**Folder: Concomitant Medication and Vaccination (1)**
**Form: Prior/Concomitant Medication and Vaccination (16)**
**Generated On: 10 Jun 2021 10:28:25**
Interval Dosage Definition (derived)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '804 (804)' | System | 16 Feb 2021 20:27:11 |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures Summary**
**Generated On: 10 Jun 2021 10:28:25**
Were any concomitant procedures performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:57:01 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:48:08 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Nick Bart (b) (4) | 02 Apr 2021 18:38:06 |
| User entered 'No (N)' | Nick Bart (b) (4) | 11 Mar 2021 19:55:09 |



FDA-CBER-2022-1614-3798627

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (1)**
**Generated On: 10 Jun 2021 10:28:25**
Procedure/Surgery date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:25:16 |
| User closed query 'Per medical records, occured 25Dec20.' (Site from CRA). | (b) (4), (b) (6) | 08 Apr 2021 18:25:14 |
| Query 'Per medical records, occured 25Dec20.' answered with 'updated' (Site from CRA). | Nick Bart (b) (4) | 08 Apr 2021 18:08:23 |
| User entered '25 Dec 2020' reason for change: Data Entry Error | Nick Bart (b) (4) | 08 Apr 2021 18:08:19 |
| User opened query 'Per medical records, occured 25Dec20.' (Site from CRA). | (b) (4), (b) (6) | 08 Apr 2021 17:44:28 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 08 Apr 2021 17:44:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 17:44:08 |
| User entered '28 Dec 2020' | Nick Bart (b) (4) | 02 Apr 2021 18:38:37 |



FDA-CBER-2022-1614-3798628

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (1)**
**Generated On: 10 Jun 2021 10:28:25**
Procedure/Surgery

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 17:44:08 |
| User entered 'CT of chest' | Nick Bart (b) (4) | 02 Apr 2021 18:38:37 |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (1)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 17:44:08 |
| User entered 'Adverse Event (AE)' | Nick Bart (b) (4) | 02 Apr 2021 18:38:37 |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (1)**
**Generated On: 10 Jun 2021 10:28:25**
If indication is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 17:44:08 |
| User entered empty. | Nick Bart (b) (4) | 02 Apr 2021 18:38:37 |



FDA-CBER-2022-1614-3798631

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (2)**
**Generated On: 10 Jun 2021 10:28:25**
Procedure/Surgery date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 17:44:08 |
| User entered '19 Jan 2021' | Nick Bart (b) (4) | 02 Apr 2021 18:43:29 |



FDA-CBER-2022-1614-3798632

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (2)**
**Generated On: 10 Jun 2021 10:28:25**
Procedure/Surgery

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 17:44:08 |
| User entered 'intubation' | Nick Bart (b) (4) | 02 Apr 2021 18:43:29 |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (2)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 17:44:08 |
| User entered 'Adverse Event (AE)' | Nick Bart (b) (4) | 02 Apr 2021 18:43:29 |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (2)**
**Generated On: 10 Jun 2021 10:28:25**
If indication is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 17:44:08 |
| User entered empty. | Nick Bart (b) (4) | 02 Apr 2021 18:43:29 |



FDA-CBER-2022-1614-3798635

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (3)**
**Generated On: 10 Jun 2021 10:28:25**
Procedure/Surgery date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 17:44:08 |
| User entered '27 Jan 2021' | Nick Bart (b) (4) | 02 Apr 2021 18:43:40 |



FDA-CBER-2022-1614-3798636

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (3)**
**Generated On: 10 Jun 2021 10:28:25**
Procedure/Surgery

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 17:44:08 |
| User entered 'bronchoscopy' | Nick Bart (b) (4) | 02 Apr 2021 18:43:40 |



FDA-CBER-2022-1614-3798637

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (3)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 17:44:08 |
| User entered 'Adverse Event (AE)' | Nick Bart (b) (4) | 02 Apr 2021 18:43:40 |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (3)**
**Generated On: 10 Jun 2021 10:28:25**
If indication is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 17:44:08 |
| User entered empty. | Nick Bart (b) (4) | 02 Apr 2021 18:43:40 |



FDA-CBER-2022-1614-3798639

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (4)**
**Generated On: 10 Jun 2021 10:28:25**
Procedure/Surgery date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:25:34 |
| User entered '28 Jan 2021' | Nick Bart (b) (4) | 08 Apr 2021 18:09:46 |



FDA-CBER-2022-1614-3798640

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (4)**
**Generated On: 10 Jun 2021 10:28:25**
Procedure/Surgery

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:25:34 |
| User entered 'blood transfusion' | Nick Bart (b) (4) | 08 Apr 2021 18:09:46 |



FDA-CBER-2022-1614-3798641

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (4)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:25:34 |
| User entered 'Adverse Event (AE)' | Nick Bart (b) (4) | 08 Apr 2021 18:09:46 |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (4)**
**Generated On: 10 Jun 2021 10:28:25**
If indication is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:25:34 |
| User entered empty. | Nick Bart (b) (4) | 08 Apr 2021 18:09:46 |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (5)**
**Generated On: 10 Jun 2021 10:28:25**
Procedure/Surgery date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:25:34 |
| User entered '05 Jan 2021' | Nick Bart (b) (4) | 08 Apr 2021 18:10:26 |



FDA-CBER-2022-1614-3798644

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (5)**
**Generated On: 10 Jun 2021 10:28:25**
Procedure/Surgery

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:25:34 |
| User entered 'ct angiography pulmonary' | Nick Bart (b) (4) | 08 Apr 2021 18:10:26 |



FDA-CBER-2022-1614-3798645

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (5)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 18:25:34 |
| User entered 'Adverse Event (AE)' | Nick Bart (b) (4) | 08 Apr 2021 18:10:26 |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (5)**
**Generated On: 10 Jun 2021 10:28:25**
If indication is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:48:08 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 18:25:34 |
| User entered empty. | Nick Bart (b) (4) | 08 Apr 2021 18:10:26 |



FDA-CBER-2022-1614-3798647

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (6)**
**Generated On: 10 Jun 2021 10:28:25**
Procedure/Surgery date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:56:45 |
| User closed query 'Future date has been entered. Please correct.' (Site from System). | System | 12 Apr 2021 22:39:30 |
| User entered '24 Dec 2020' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:39:30 |
| User opened query 'Future date has been entered. Please correct.' (Site from System). | System | 12 Apr 2021 22:39:23 |
| User entered '24 Dec 2021' | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:39:23 |



FDA-CBER-2022-1614-3798648

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (6)**
**Generated On: 10 Jun 2021 10:28:25**
Procedure/Surgery

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:56:45 |
| User entered 'X-Ray of Chest' | Atanas Filev (b) (4)<br>(b) (4) | 12 Apr 2021 22:39:23 |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (6)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:56:45 |
| User entered 'Adverse Event (AE)' | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:39:23 |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (6)**
**Generated On: 10 Jun 2021 10:28:25**
If indication is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:56:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 12 Apr 2021 22:39:23 |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (7)**
**Generated On: 10 Jun 2021 10:28:25**
Procedure/Surgery date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:56:45 |
| User entered '13 Jan 2021' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 00:26:47 |



FDA-CBER-2022-1614-3798652

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (7)**
**Generated On: 10 Jun 2021 10:28:25**
Procedure/Surgery

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:56:45 |
| User entered 'X-Ray of the chest' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 00:26:47 |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (7)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:56:45 |
| User entered 'Adverse Event (AE)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 00:26:47 |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (7)**
**Generated On: 10 Jun 2021 10:28:25**
If indication is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:56:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 00:26:47 |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (8)**
**Generated On: 10 Jun 2021 10:28:25**
Procedure/Surgery date *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:56:45 |
| User entered '26 Jan 2021' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 00:30:26 |



FDA-CBER-2022-1614-3798656

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (8)**
**Generated On: 10 Jun 2021 10:28:25**
Procedure/Surgery

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:56:45 |
| User entered 'X-Ray of the chest' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 00:30:26 |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (8)**
**Generated On: 10 Jun 2021 10:28:25**
Indication

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:56:45 |
| User entered 'Adverse Event (AE)' | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 00:30:26 |

**US3952094**
**Folder: Concomitant Procedures (1)**
**Form: Concomitant Procedures (8)**
**Generated On: 10 Jun 2021 10:28:25**
If indication is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:56:45 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 13 Apr 2021 00:30:26 |

**US3952094**
**Folder: End of Study (1)**
**Form: End of Study / Study Discontinuation**
**Generated On: 10 Jun 2021 10:28:25**
Date of study discontinuation/completion *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User closed query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System). | System | 14 Apr 2021 17:48:47 |
| User entered '30 Jan 2021' reason for change: Data Entry Error | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 17:48:47 |
| User opened query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System). | System | 14 Apr 2021 17:40:56 |
| User entered '04 Feb 2021' | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 17:40:56 |

**US3952094**
**Folder: End of Study (1)**
**Form: End of Study / Study Discontinuation**
**Generated On: 10 Jun 2021 10:28:25**
Reason for discontinuation

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Death (DEATH)' | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 17:40:56 |

**US3952094**
**Folder: End of Study (1)**
**Form: End of Study / Study Discontinuation**
**Generated On: 10 Jun 2021 10:28:25**
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 17:40:56 |

**US3952094**
**Folder: End of Study (1)**
**Form: End of Study / Study Discontinuation**
**Generated On: 10 Jun 2021 10:28:25**
If reason for discontinuation is Death, main cause of death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'Adverse event (ADVERSE EVENT)' | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 17:40:56 |

**US3952094**
**Folder: End of Study (1)**
**Form: End of Study / Study Discontinuation**
**Generated On: 10 Jun 2021 10:28:25**
If main cause of death is Other, specify

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered empty. | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 17:40:56 |

**US3952094**
**Folder: End of Study (1)**
**Form: End of Study / Study Discontinuation**
**Generated On: 10 Jun 2021 10:28:25**
Date of death *(dd MMM yyyy)*

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered '30 Jan 2021' | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 17:40:56 |



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**US3952094**
**Folder: End of Study (1)**
**Form: End of Study / Study Discontinuation**
**Generated On: 10 Jun 2021 10:28:25**
Was autopsy performed?

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 16 Apr 2021 16:32:55 |
| User entered 'No (N)' | Atanas Filev (b) (4) (b) (4) | 14 Apr 2021 17:40:56 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
SAEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'USA-US215-2021-MRNA-1273-P301000001' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Serious

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Feb 2021 18:45:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Feb 2021 17:59:38 |
| Un-reviewed for Safety. | System | 08 Feb 2021 15:08:35 |
| DataPoint Un-verified. | System | 08 Feb 2021 15:08:35 |
| Signature has been broken. | System | 08 Feb 2021 15:08:35 |
| User entered 'Yes (Y)' | System | 08 Feb 2021 15:08:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |



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**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's First Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Mimi' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's Last Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Van Der Leden' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Street

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '15201 Shady Grove Dr' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: City

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Rockville' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: State

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User entered empty. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:44 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Postal Code

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '20850' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator Country

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered 'US' | (b) (4) System | 04 Jan 2021 18:28:16 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
E2B Transmit Flag (Derived/Hidden)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '9' | System | 12 Apr 2021 20:08:24 |
| User entered '8' | System | 09 Apr 2021 15:58:47 |
| User entered '7' | System | 05 Apr 2021 16:16:09 |
| User entered '6' | System | 17 Feb 2021 16:42:34 |
| User entered '5' | System | 09 Feb 2021 18:45:49 |
| User entered '4' | System | 29 Jan 2021 19:54:23 |
| User entered '3' | System | 29 Jan 2021 19:42:07 |
| Signature has been broken. | System | 07 Jan 2021 16:57:05 |
| User entered '2' | System | 07 Jan 2021 16:57:05 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered '1' | (b) (4) System | 04 Jan 2021 18:28:16 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
SAEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'USA-US215-2021-MRNA-1273-P301000001' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Serious

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Feb 2021 18:45:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Feb 2021 17:59:38 |
| Un-reviewed for Safety. | System | 08 Feb 2021 15:08:35 |
| DataPoint Un-verified. | System | 08 Feb 2021 15:08:35 |
| Signature has been broken. | System | 08 Feb 2021 15:08:35 |
| User entered 'Yes (Y)' | System | 08 Feb 2021 15:08:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's First Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Mimi' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's Last Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Van Der Leden' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Street

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '15201 Shady Grove Dr' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: City

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Rockville' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: State

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User entered empty. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:44 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Postal Code

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '20850' | System | 04 Jan 2021 18:27:47 |



FDA-CBER-2022-1614-3798696

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator Country

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered 'US' | (b) (4) System | 04 Jan 2021 18:28:16 |



FDA-CBER-2022-1614-3798697

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
E2B Transmit Flag (Derived/Hidden)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '9' | System | 12 Apr 2021 20:08:24 |
| User entered '8' | System | 09 Apr 2021 15:58:47 |
| User entered '7' | System | 05 Apr 2021 16:16:09 |
| User entered '6' | System | 17 Feb 2021 16:42:34 |
| User entered '5' | System | 09 Feb 2021 18:45:49 |
| User entered '4' | System | 29 Jan 2021 19:54:23 |
| User entered '3' | System | 29 Jan 2021 19:42:07 |
| Signature has been broken. | System | 07 Jan 2021 16:57:05 |
| User entered '2' | System | 07 Jan 2021 16:57:05 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered '1' | (b) (4) System | 04 Jan 2021 18:28:16 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (1)**
**Generated On: 10 Jun 2021 10:28:25**
Date of submission (Pre-filled from custom function)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered '04/Jan/2021 18:28' | (b) (4) System | 04 Jan 2021 18:28:16 |

**US3952094**

**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 10:28:25**

**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) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:20 |
| User entered '1' | (b) (4), (b) (6) | 04 Jan 2021 18:28:16 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
SAEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'USA-US215-2021-MRNA-1273-P301000001' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Serious

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 09 Feb 2021 18:45:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Feb 2021 17:59:38 |
| Un-reviewed for Safety. | System | 08 Feb 2021 15:08:35 |
| DataPoint Un-verified. | System | 08 Feb 2021 15:08:35 |
| Signature has been broken. | System | 08 Feb 2021 15:08:35 |
| User entered 'Yes (Y)' | System | 08 Feb 2021 15:08:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |



FDA-CBER-2022-1614-3798708

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's First Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Mimi' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's Last Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Van Der Leden' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Street

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '15201 Shady Grove Dr' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: City

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Rockville' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: State

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User entered empty. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:44 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Postal Code

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '20850' | System | 04 Jan 2021 18:27:47 |



FDA-CBER-2022-1614-3798714

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator Country

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered 'US' | (b) (4) System | 04 Jan 2021 18:28:16 |



FDA-CBER-2022-1614-3798715

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
E2B Transmit Flag (Derived/Hidden)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '9' | System | 12 Apr 2021 20:08:24 |
| User entered '8' | System | 09 Apr 2021 15:58:47 |
| User entered '7' | System | 05 Apr 2021 16:16:09 |
| User entered '6' | System | 17 Feb 2021 16:42:34 |
| User entered '5' | System | 09 Feb 2021 18:45:49 |
| User entered '4' | System | 29 Jan 2021 19:54:23 |
| User entered '3' | System | 29 Jan 2021 19:42:07 |
| Signature has been broken. | System | 07 Jan 2021 16:57:05 |
| User entered '2' | System | 07 Jan 2021 16:57:05 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered '1' | (b) (4) System | 04 Jan 2021 18:28:16 |



FDA-CBER-2022-1614-3798716

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (2)**
**Generated On: 10 Jun 2021 10:28:25**
Date of submission (Pre-filled from custom function)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:57:45 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:49:27 |
| User entered '07/Jan/2021 11:57' | (b) (4) System | 07 Jan 2021 16:57:05 |

**US3952094**

**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 10:28:25**

**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) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:57:45 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Jan 2021 19:41:55 |
| User entered '1' | (b) (4), (b) (6) | 07 Jan 2021 16:57:05 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
SAEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'USA-US215-2021-MRNA-1273-P301000001' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Serious

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Feb 2021 18:45:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Feb 2021 17:59:38 |
| Un-reviewed for Safety. | System | 08 Feb 2021 15:08:35 |
| DataPoint Un-verified. | System | 08 Feb 2021 15:08:35 |
| Signature has been broken. | System | 08 Feb 2021 15:08:35 |
| User entered 'Yes (Y)' | System | 08 Feb 2021 15:08:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |



FDA-CBER-2022-1614-3798726

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's First Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Mimi' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's Last Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Van Der Leden' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Street

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '15201 Shady Grove Dr' | System | 04 Jan 2021 18:27:47 |



FDA-CBER-2022-1614-3798729

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: City

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Rockville' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: State

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User entered empty. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:44 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Postal Code

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '20850' | System | 04 Jan 2021 18:27:47 |



FDA-CBER-2022-1614-3798732

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator Country

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered 'US' | (b) (4) System | 04 Jan 2021 18:28:16 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
E2B Transmit Flag (Derived/Hidden)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '9' | System | 12 Apr 2021 20:08:24 |
| User entered '8' | System | 09 Apr 2021 15:58:47 |
| User entered '7' | System | 05 Apr 2021 16:16:09 |
| User entered '6' | System | 17 Feb 2021 16:42:34 |
| User entered '5' | System | 09 Feb 2021 18:45:49 |
| User entered '4' | System | 29 Jan 2021 19:54:23 |
| User entered '3' | System | 29 Jan 2021 19:42:07 |
| Signature has been broken. | System | 07 Jan 2021 16:57:05 |
| User entered '2' | System | 07 Jan 2021 16:57:05 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered '1' | (b) (4) System | 04 Jan 2021 18:28:16 |



FDA-CBER-2022-1614-3798734

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (3)**
**Generated On: 10 Jun 2021 10:28:25**
Date of submission (Pre-filled from custom function)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:57:45 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:49:27 |
| User entered '29/Jan/2021 19:42' | (b) (4) System | 29 Jan 2021 19:42:07 |

**US3952094**

**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 10:28:25**

**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) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:57:45 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Jan 2021 19:54:11 |
| User entered '1' | (b) (4), (b) (6) | 29 Jan 2021 19:42:07 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
SAEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'USA-US215-2021-MRNA-1273-P301000001' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Serious

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Feb 2021 18:45:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Feb 2021 17:59:38 |
| Un-reviewed for Safety. | System | 08 Feb 2021 15:08:35 |
| DataPoint Un-verified. | System | 08 Feb 2021 15:08:35 |
| Signature has been broken. | System | 08 Feb 2021 15:08:35 |
| User entered 'Yes (Y)' | System | 08 Feb 2021 15:08:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |



FDA-CBER-2022-1614-3798741

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |



FDA-CBER-2022-1614-3798744

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's First Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Mimi' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's Last Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Van Der Leden' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Street

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '15201 Shady Grove Dr' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: City

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Rockville' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: State

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User entered empty. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:44 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Postal Code

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '20850' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator Country

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered 'US' | (b) (4) System | 04 Jan 2021 18:28:16 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
E2B Transmit Flag (Derived/Hidden)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '9' | System | 12 Apr 2021 20:08:24 |
| User entered '8' | System | 09 Apr 2021 15:58:47 |
| User entered '7' | System | 05 Apr 2021 16:16:09 |
| User entered '6' | System | 17 Feb 2021 16:42:34 |
| User entered '5' | System | 09 Feb 2021 18:45:49 |
| User entered '4' | System | 29 Jan 2021 19:54:23 |
| User entered '3' | System | 29 Jan 2021 19:42:07 |
| Signature has been broken. | System | 07 Jan 2021 16:57:05 |
| User entered '2' | System | 07 Jan 2021 16:57:05 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered '1' | (b) (4) System | 04 Jan 2021 18:28:16 |



FDA-CBER-2022-1614-3798752

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (4)**
**Generated On: 10 Jun 2021 10:28:25**
Date of submission (Pre-filled from custom function)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:57:45 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:49:27 |
| User entered '29/Jan/2021 19:54' | (b) (4) System | 29 Jan 2021 19:54:23 |

**US3952094**

**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 10:28:25**

**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) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:57:45 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Feb 2021 18:45:40 |
| User entered '1' | (b) (4), (b) (6) | 29 Jan 2021 19:54:23 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
SAEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'USA-US215-2021-MRNA-1273-P301000001' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Serious

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Feb 2021 18:45:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Feb 2021 17:59:38 |
| Un-reviewed for Safety. | System | 08 Feb 2021 15:08:35 |
| DataPoint Un-verified. | System | 08 Feb 2021 15:08:35 |
| Signature has been broken. | System | 08 Feb 2021 15:08:35 |
| User entered 'Yes (Y)' | System | 08 Feb 2021 15:08:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's First Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Mimi' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's Last Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Van Der Leden' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Street

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '15201 Shady Grove Dr' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: City

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Rockville' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: State

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User entered empty. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:44 |



FDA-CBER-2022-1614-3798767

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Postal Code

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '20850' | System | 04 Jan 2021 18:27:47 |



FDA-CBER-2022-1614-3798768

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator Country

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered 'US' | (b) (4) System | 04 Jan 2021 18:28:16 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
E2B Transmit Flag (Derived/Hidden)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '9' | System | 12 Apr 2021 20:08:24 |
| User entered '8' | System | 09 Apr 2021 15:58:47 |
| User entered '7' | System | 05 Apr 2021 16:16:09 |
| User entered '6' | System | 17 Feb 2021 16:42:34 |
| User entered '5' | System | 09 Feb 2021 18:45:49 |
| User entered '4' | System | 29 Jan 2021 19:54:23 |
| User entered '3' | System | 29 Jan 2021 19:42:07 |
| Signature has been broken. | System | 07 Jan 2021 16:57:05 |
| User entered '2' | System | 07 Jan 2021 16:57:05 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered '1' | (b) (4) System | 04 Jan 2021 18:28:16 |



FDA-CBER-2022-1614-3798770

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (5)**
**Generated On: 10 Jun 2021 10:28:25**
Date of submission (Pre-filled from custom function)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:57:45 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:49:27 |
| User entered '09/Feb/2021 18:45' | (b) (4) System | 09 Feb 2021 18:45:49 |

**US3952094**

**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 10:28:25**

**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) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:57:45 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Feb 2021 16:42:18 |
| User entered '1' | (b) (4), (b) (6) | 09 Feb 2021 18:45:49 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
SAEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'USA-US215-2021-MRNA-1273-P301000001' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Serious

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Feb 2021 18:45:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Feb 2021 17:59:38 |
| Un-reviewed for Safety. | System | 08 Feb 2021 15:08:35 |
| DataPoint Un-verified. | System | 08 Feb 2021 15:08:35 |
| Signature has been broken. | System | 08 Feb 2021 15:08:35 |
| User entered 'Yes (Y)' | System | 08 Feb 2021 15:08:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's First Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Mimi' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's Last Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Van Der Leden' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Street

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '15201 Shady Grove Dr' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: City

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Rockville' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: State

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User entered empty. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:44 |



FDA-CBER-2022-1614-3798785

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Postal Code

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '20850' | System | 04 Jan 2021 18:27:47 |



FDA-CBER-2022-1614-3798786

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator Country

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered 'US' | (b) (4) System | 04 Jan 2021 18:28:16 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
E2B Transmit Flag (Derived/Hidden)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '9' | System | 12 Apr 2021 20:08:24 |
| User entered '8' | System | 09 Apr 2021 15:58:47 |
| User entered '7' | System | 05 Apr 2021 16:16:09 |
| User entered '6' | System | 17 Feb 2021 16:42:34 |
| User entered '5' | System | 09 Feb 2021 18:45:49 |
| User entered '4' | System | 29 Jan 2021 19:54:23 |
| User entered '3' | System | 29 Jan 2021 19:42:07 |
| Signature has been broken. | System | 07 Jan 2021 16:57:05 |
| User entered '2' | System | 07 Jan 2021 16:57:05 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered '1' | (b) (4) System | 04 Jan 2021 18:28:16 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (6)**
**Generated On: 10 Jun 2021 10:28:25**
Date of submission (Pre-filled from custom function)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:57:45 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:49:27 |
| User entered '17/Feb/2021 11:42' | (b) (4) System | 17 Feb 2021 16:42:34 |

**US3952094**

**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 10:28:25**

**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) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:57:45 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Apr 2021 16:18:05 |
| User entered '1' | (b) (4), (b) (6) | 17 Feb 2021 16:42:34 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
SAEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'USA-US215-2021-MRNA-1273-P301000001' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Serious

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 09 Feb 2021 18:45:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Feb 2021 17:59:38 |
| Un-reviewed for Safety. | System | 08 Feb 2021 15:08:35 |
| DataPoint Un-verified. | System | 08 Feb 2021 15:08:35 |
| Signature has been broken. | System | 08 Feb 2021 15:08:35 |
| User entered 'Yes (Y)' | System | 08 Feb 2021 15:08:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |



FDA-CBER-2022-1614-3798798

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's First Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Mimi' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's Last Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Van Der Leden' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Street

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '15201 Shady Grove Dr' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: City

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Rockville' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: State

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User entered empty. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:44 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Postal Code

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '20850' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator Country

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered 'US' | (b) (4) System | 04 Jan 2021 18:28:16 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
E2B Transmit Flag (Derived/Hidden)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '9' | System | 12 Apr 2021 20:08:24 |
| User entered '8' | System | 09 Apr 2021 15:58:47 |
| User entered '7' | System | 05 Apr 2021 16:16:09 |
| User entered '6' | System | 17 Feb 2021 16:42:34 |
| User entered '5' | System | 09 Feb 2021 18:45:49 |
| User entered '4' | System | 29 Jan 2021 19:54:23 |
| User entered '3' | System | 29 Jan 2021 19:42:07 |
| Signature has been broken. | System | 07 Jan 2021 16:57:05 |
| User entered '2' | System | 07 Jan 2021 16:57:05 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered '1' | (b) (4) System | 04 Jan 2021 18:28:16 |



FDA-CBER-2022-1614-3798806

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (7)**
**Generated On: 10 Jun 2021 10:28:25**
Date of submission (Pre-filled from custom function)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:57:45 |
| User signature succeeded. | Mimi Van Der Leden | 08 Apr 2021 19:49:27 |
| User entered '05/Apr/2021 12:16' | (b) (4) System | 05 Apr 2021 16:16:09 |

**US3952094**

**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 10:28:25**

**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) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:57:45 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Apr 2021 16:18:05 |
| User entered '1' | (b) (4), (b) (6) | 05 Apr 2021 16:16:09 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
SAEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'USA-US215-2021-MRNA-1273-P301000001' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Serious

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Feb 2021 18:45:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Feb 2021 17:59:38 |
| Un-reviewed for Safety. | System | 08 Feb 2021 15:08:35 |
| DataPoint Un-verified. | System | 08 Feb 2021 15:08:35 |
| Signature has been broken. | System | 08 Feb 2021 15:08:35 |
| User entered 'Yes (Y)' | System | 08 Feb 2021 15:08:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |



FDA-CBER-2022-1614-3798816

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's First Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Mimi' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's Last Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Van Der Leden' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Street

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '15201 Shady Grove Dr' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: City

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Rockville' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: State

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User entered empty. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:44 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Postal Code

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '20850' | System | 04 Jan 2021 18:27:47 |



FDA-CBER-2022-1614-3798822

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator Country

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered 'US' | (b) (4) System | 04 Jan 2021 18:28:16 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
E2B Transmit Flag (Derived/Hidden)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '9' | System | 12 Apr 2021 20:08:24 |
| User entered '8' | System | 09 Apr 2021 15:58:47 |
| User entered '7' | System | 05 Apr 2021 16:16:09 |
| User entered '6' | System | 17 Feb 2021 16:42:34 |
| User entered '5' | System | 09 Feb 2021 18:45:49 |
| User entered '4' | System | 29 Jan 2021 19:54:23 |
| User entered '3' | System | 29 Jan 2021 19:42:07 |
| Signature has been broken. | System | 07 Jan 2021 16:57:05 |
| User entered '2' | System | 07 Jan 2021 16:57:05 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered '1' | (b) (4) System | 04 Jan 2021 18:28:16 |



FDA-CBER-2022-1614-3798824

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (8)**
**Generated On: 10 Jun 2021 10:28:25**
Date of submission (Pre-filled from custom function)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:57:45 |
| User signature succeeded. | Mimi Van Der Leden | 09 Apr 2021 20:15:44 |
| User entered '09/Apr/2021 10:58' | (b) (4) System | 09 Apr 2021 15:58:47 |

**US3952094**

**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (8)**

**Generated On: 10 Jun 2021 10:28:25**

**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) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:57:45 |
| User signature succeeded. | Mimi Van Der Leden | 09 Apr 2021 20:15:44 |
| User entered '1' | (b) (4), (b) (6) | 09 Apr 2021 15:58:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
SAEID

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'USA-US215-2021-MRNA-1273-P301000001' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Serious

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Death

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Feb 2021 18:45:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Feb 2021 17:59:38 |
| Un-reviewed for Safety. | System | 08 Feb 2021 15:08:35 |
| DataPoint Un-verified. | System | 08 Feb 2021 15:08:35 |
| Signature has been broken. | System | 08 Feb 2021 15:08:35 |
| User entered 'Yes (Y)' | System | 08 Feb 2021 15:08:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Life threatening

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Yes (Y)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |



FDA-CBER-2022-1614-3798832

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Congenital anomaly or birth defect

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Other medically important event

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'No (N)' | System | 04 Jan 2021 18:27:47 |



FDA-CBER-2022-1614-3798834

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's First Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Mimi' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator's Last Name

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Van Der Leden' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Street

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '15201 Shady Grove Dr' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: City

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered 'Rockville' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: State

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden (b) (4) | 08 Apr 2021 19:49:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User entered empty. | Mimi Van Der Leden (b) (4) | 05 Jan 2021 14:26:44 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Site Address: Postal Code

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Jan 2021 18:28:08 |
| User entered '20850' | System | 04 Jan 2021 18:27:47 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
Investigator Country

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 16:56:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 15:33:16 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered 'US' | (b) (4) System | 04 Jan 2021 18:28:16 |

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form**
**Generated On: 10 Jun 2021 10:28:25**
E2B Transmit Flag (Derived/Hidden)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User entered '9' | System | 12 Apr 2021 20:08:24 |
| User entered '8' | System | 09 Apr 2021 15:58:47 |
| User entered '7' | System | 05 Apr 2021 16:16:09 |
| User entered '6' | System | 17 Feb 2021 16:42:34 |
| User entered '5' | System | 09 Feb 2021 18:45:49 |
| User entered '4' | System | 29 Jan 2021 19:54:23 |
| User entered '3' | System | 29 Jan 2021 19:42:07 |
| Signature has been broken. | System | 07 Jan 2021 16:57:05 |
| User entered '2' | System | 07 Jan 2021 16:57:05 |
| User signature succeeded. | Mimi Van Der Leden | 05 Jan 2021 14:26:20 |
| User entered '1' | (b) (4) System | 04 Jan 2021 18:28:16 |



FDA-CBER-2022-1614-3798842

**US3952094**
**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**
**Form: Safety Report Form (9)**
**Generated On: 10 Jun 2021 10:28:25**
Date of submission (Pre-filled from custom function)

| Audit | User | Time (GMT) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:57:45 |
| User entered '12/Apr/2021 15:08' | System | 12 Apr 2021 20:08:24 |

**US3952094**

**Folder: SAE USA-US215-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (9)**

**Generated On: 10 Jun 2021 10:28:25**

**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) |
|---|---|---|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:12:42 |
| User signature succeeded. | Mimi Van Der Leden | 16 Apr 2021 16:32:55 |
| DataPoint Verified. | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 16:57:45 |
| User entered '1' | (b) (4), (b) (6) | 12 Apr 2021 20:08:24 |