US3522042 (Prod: Henry Ford Health System)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:50:46

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US3522042
Form: Participant Creation
Data signed: (b) (4) **21 Feb 2021 21:15:22**
Generated On: 11 Aug 2021 22:50:46

Participant ID	US3522042

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0808181

US3522042
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **21 Feb 2021 21:15:47**
Generated On: 11 Aug 2021 22:50:46

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-0808182

US3522042
Folder: Screening
Form: Demographics
Data signed: (b) (4) **21 Feb 2021 21:15:47**
Generated On: 11 Aug 2021 22:50:46

Date of Birth (MMM yyyy)	(b) (6) 1985
Age	34
Age Units	YEARS
Age (Derived)	34
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-2022-1614-0808183

US3522042
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **21 Feb 2021 21:15:47**
Generated On: 11 Aug 2021 22:50:46

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

FDA-CBER-2022-1614-0808184

US3522042
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **21 Feb 2021 21:15:47**
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Did the participant meet all eligibility criteria?	Yes ■ No ☐

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US3522042
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **21 Feb 2021 21:15:47**
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Were any significant conditions reported?	Yes ■ No ☐

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US3522042
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **21 Feb 2021 21:15:47**
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Condition	HYPERTENSION
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0808187

US3522042
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **21 Feb 2021 21:15:47**
Generated On: 11 Aug 2021 22:50:46

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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US3522042
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **21 Feb 2021 21:15:48**
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Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	07 AUG 2020
Time of assessment *(00:00-23:59)*	09:55 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 09:55
Height *(xxx.x)*	67 in
Weight *(xxx.x)*	178.2 lb
BMI *(xxx.x)*	27.96842 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ☐ Axillary ☐ 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)	

FDA-CBER-2022-1614-0808189

US3522042
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **21 Feb 2021 21:15:47**
Generated On: 11 Aug 2021 22:50:46

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	07 AUG 2020

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

FDA-CBER-2022-1614-0808190

US3522042
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **21 Feb 2021 21:15:47**
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Occupational Risk	
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ■ No ☐
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐ No ■
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐ No ■
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐ No ■
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐ No ■
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐ No ■
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐ No ■
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐ No ■
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐ No ■
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐ No ■
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐ No ■
Other	Yes ☐ No ■
Specify	

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

FDA-CBER-2022-1614-0808191

US3522042
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **21 Feb 2021 21:15:47**
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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

FDA-CBER-2022-1614-0808192

US3522042
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **16 Feb 2021 16:49:43**
Generated On: 11 Aug 2021 22:50:46

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-0808193

US3522042
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **16 Feb 2021 16:49:43**
Generated On: 11 Aug 2021 22:50:46

What was the date of randomization? *(dd MMM yyyy)*	07 AUG 2020
What was the participant's randomization number?	101710
In what Cohort was the participant enrolled?	>=18 and <65 years and not at risk ■ >=18 and <65 years and at risk ☐ >=65 years ☐

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)	Yes ☐ No ■
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes ☐ No ■
Severe obesity (body mass index > or = 40kg/m2	Yes ☐ No ■
Diabetes (Type I, Type 2, or gestational)	Yes ☐ No ■
Liver Disease	Yes ☐ No ■

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US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **16 Feb 2021 16:49:44**
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Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-0808195

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **16 Feb 2021 16:49:44**
Generated On: 11 Aug 2021 22:50:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	7 AUG 2020
Time of assessment *(00:00-23:59)*	09:55 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 09:55
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	65 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	91 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0808196

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **16 Feb 2021 16:49:44**
Generated On: 11 Aug 2021 22:50:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ○ Post-Dose ●
Were vital signs assessed?	Yes ● No ○
Date of assessment *(dd MMM yyyy)*	7 AUG 2020
Time of assessment *(00:00-23:59)*	11:20 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 11:20
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ● Axillary ○ Other ○
If Other, specify	
Pulse *(xxx)*	54 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	90 mmHg
Diastolic Blood Pressure units	MMHG

US3522042
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **16 Feb 2021 16:49:43**
Generated On: 11 Aug 2021 22:50:46

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.

FDA-CBER-2022-1614-0808198

US3522042
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **16 Feb 2021 16:49:43**
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Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	7 AUG 2020
What was the treatment time? *(00:00-23:59)*	10:50 (24 HR)
Treatment Date and Time (derived)	7 AUG 2020 10:50
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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US3522042
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **16 Feb 2021 16:49:43**
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Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	7 AUG 2020
Collection time *(00:00-23:59)*	09:47 (24 HR)
Collection date and time (derived)	7 AUG 2020 09:47

FDA-CBER-2022-1614-0808200

US3522042
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **16 Feb 2021 16:49:43**
Generated On: 11 Aug 2021 22:50:46

Collection date *(dd MMM yyyy)*			7 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:35	7 AUG 2020 09:35
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0808201

US3522042
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **16 Feb 2021 16:49:43**
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Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0808202

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:50:46

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	07 AUG 2020 11:20
PC Open Date & Time	07 AUG 2020 11:20
PC Close Date & Time	07 AUG 2020 13:50

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	07 AUG 2020 14:50
PC Open Date & Time	07 AUG 2020 14:45
PC Close Date & Time	08 AUG 2020 11:59

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**	97.0 °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	08 AUG 2020 12:04
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	09 AUG 2020 14:46
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

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TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	96.8 °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	10 AUG 2020 16:07
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

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**	97.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	11 AUG 2020 12:24
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

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Form: Temperature_Day(6)
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TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	12 AUG 2020 13:49
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	13 AUG 2020 12:18
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:50:46

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	07 AUG 2020 11:21
PC Open Date & Time	07 AUG 2020 11:20
PC Close Date & Time	07 AUG 2020 13:50

FDA-CBER-2022-1614-0808211

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:50:46

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	07 AUG 2020 14:45
PC Open Date & Time	07 AUG 2020 14:45
PC Close Date & Time	08 AUG 2020 11:59

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:50:46

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	08 AUG 2020 12:00
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:50:46

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	09 AUG 2020 14:45
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

FDA-CBER-2022-1614-0808214

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:50:46

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	10 AUG 2020 16:07
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

FDA-CBER-2022-1614-0808215

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:50:46

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

FDA-CBER-2022-1614-0808216

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:50:46

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	12 AUG 2020 13:50
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-0808217

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:50:46

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	13 AUG 2020 12:18
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

FDA-CBER-2022-1614-0808218

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

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:50:46

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	07 AUG 2020 11:21
PC Open Date & Time	07 AUG 2020 11:20
PC Close Date & Time	07 AUG 2020 13:50

FDA-CBER-2022-1614-0808220

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 ☐

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:50:46

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	07 AUG 2020 14:45
PC Open Date & Time	07 AUG 2020 14:45
PC Close Date & Time	08 AUG 2020 11:59

FDA-CBER-2022-1614-0808222

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808223

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:50:46

	Yes
PC Time stamp	08 AUG 2020 12:00
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

FDA-CBER-2022-1614-0808224

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808225

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:50:46

	Yes
PC Time stamp	09 AUG 2020 14:45
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

FDA-CBER-2022-1614-0808226

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808227

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:50:46

	Yes ☐
PC Time stamp	10 AUG 2020 16:07
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

FDA-CBER-2022-1614-0808228

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 ■

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:50:46

	Yes ☐
PC Time stamp	11 AUG 2020 12:23
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

FDA-CBER-2022-1614-0808230

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 ■

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:50:46

	Yes ☐
PC Time stamp	12 AUG 2020 13:50
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-0808232

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 ■

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:50:46

	Yes ☐
PC Time stamp	13 AUG 2020 12:19
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

FDA-CBER-2022-1614-0808234

US3522042
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **16 Feb 2021 16:49:43**
Generated On: 11 Aug 2021 22:50:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 AUG 2020
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ■
Comments *If Contact Not Made, please provide Comments*	ATTEMPTED TO CALL PATIENT, DID NOT ANSWER; VOICEMAIL WAS LEFT

FDA-CBER-2022-1614-0808235

US3522042
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **16 Feb 2021 16:49:43**
Generated On: 11 Aug 2021 22:50:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0808236

US3522042
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **16 Feb 2021 16:49:43**
Generated On: 11 Aug 2021 22:50:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	21 AUG 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	PT IS GOOD, NO ADVERSE EVENTS

FDA-CBER-2022-1614-0808237

US3522042
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **16 Feb 2021 16:49:43**
Generated On: 11 Aug 2021 22:50:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0808238

US3522042
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **16 Feb 2021 16:49:43**
Generated On: 11 Aug 2021 22:50:46

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

FDA-CBER-2022-1614-0808239

US3522042
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **16 Feb 2021 16:49:43**
Generated On: 11 Aug 2021 22:50:46

Is the participant continuing to the next visit?	Yes ☐ No ■
Continuing Flag	

FDA-CBER-2022-1614-0808240

US3522042
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **16 Feb 2021 16:49:44**
Generated On: 11 Aug 2021 22:50:46

Was this visit performed?	Yes ☐ No ■
Visit date (dd MMM yyyy)	
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☐
Folder OID	VISIT2

FDA-CBER-2022-1614-0808241

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing
Data signed: (b) (4) **16 Feb 2021 16:49:44**
Generated On: 11 Aug 2021 22:50:46

Height	
Weight	

FDA-CBER-2022-1614-0808242

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **16 Feb 2021 16:49:44**
Generated On: 11 Aug 2021 22:50:46

Height	
Weight	
Timepoint	Pre-Dose ■ Post-Dose ☐
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	

FDA-CBER-2022-1614-0808243

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **16 Feb 2021 16:49:44**
Generated On: 11 Aug 2021 22:50:46

Height	
Weight	
Timepoint	Pre-Dose ☐ Post-Dose ■
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	

FDA-CBER-2022-1614-0808244

US3522042
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **16 Feb 2021 16:49:44**
Generated On: 11 Aug 2021 22:50:46

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.

FDA-CBER-2022-1614-0808245

US3522042
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **16 Feb 2021 16:49:44**
Generated On: 11 Aug 2021 22:50:46

Was study treatment given?	Yes ☐ No ■
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ■ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	
What was the treatment date? *(dd MMM yyyy)*	
What was the treatment time? *(00:00-23:59)*	
Treatment Date and Time (derived)	
Which arm was used to give treatment?	Left Arm ☐ Right Arm ☐
What was the frequency of the study treatment dosing?	
What was the route of administration for the study treatment?	

FDA-CBER-2022-1614-0808246

US3522042
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **16 Feb 2021 16:49:44**
Generated On: 11 Aug 2021 22:50:46

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

FDA-CBER-2022-1614-0808247

US3522042
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **16 Feb 2021 16:49:44**
Generated On: 11 Aug 2021 22:50:46

Collection date *(dd MMM yyyy)*

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

FDA-CBER-2022-1614-0808248

US3522042
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **16 Feb 2021 16:49:44**
Generated On: 11 Aug 2021 22:50:46

Is the participant continuing to the next visit?	Yes ☐ No ■
Continuing Flag	

FDA-CBER-2022-1614-0808249

US3522042
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **16 Feb 2021 16:49:43**
Generated On: 11 Aug 2021 22:50:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	10 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	PATIENT WAS COVID-POSITIVE; PHYSICIAN DR. RAMESH WAS PERFORMING ACTIVE TELEMEDICINE AND ILLNESS VISITS IN LIEU OF SAFETY PHONE CALLS

FDA-CBER-2022-1614-0808250

US3522042
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **16 Feb 2021 16:49:43**
Generated On: 11 Aug 2021 22:50:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0808251

US3522042
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **16 Feb 2021 16:49:43**
Generated On: 11 Aug 2021 22:50:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	17 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	PATIENT WAS COVID-POSITIVE; PHYSICIAN DR. RAMESH WAS PERFORMING ACTIVE TELEMEDICINE AND ILLNESS VISITS IN LIEU OF SAFETY PHONE CALLS

FDA-CBER-2022-1614-0808252

US3522042
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **16 Feb 2021 16:49:43**
Generated On: 11 Aug 2021 22:50:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0808253

US3522042
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **16 Feb 2021 16:49:43**
Generated On: 11 Aug 2021 22:50:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	29 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	PATIENT WAS COVID POSITIVE, DID NOT RECEIVE SECOND DOSAGE HAS BEEN DOING ILLNESS VISITS WITH STUDY DOCTOR.

FDA-CBER-2022-1614-0808254

US3522042
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **16 Feb 2021 16:49:43**
Generated On: 11 Aug 2021 22:50:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0808255

US3522042
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **16 Feb 2021 16:49:44**
Generated On: 11 Aug 2021 22:50:46

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	2 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-0808256

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **16 Feb 2021 16:49:44**
Generated On: 11 Aug 2021 22:50:46

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	02 OCT 2020
Time of assessment *(00:00-23:59)*	09:30 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 09:30
Temperature *(xxx.x)*	97.6 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	59 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0808257

US3522042
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **16 Feb 2021 16:49:44**
Generated On: 11 Aug 2021 22:50:46

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	2 OCT 2020

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

FDA-CBER-2022-1614-0808258

US3522042
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **16 Feb 2021 16:49:44**
Generated On: 11 Aug 2021 22:50:46

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	2 OCT 2020
Collection time *(00:00-23:59)*	09:40 (24 HR)
Collection date and time (derived)	2 OCT 2020 09:40

FDA-CBER-2022-1614-0808259

US3522042
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **16 Feb 2021 16:49:44**
Generated On: 11 Aug 2021 22:50:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0808260

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 OCT 2020 10:07:47
Patient Cloud Open Date & Time	07 OCT 2020 00:01
Patient Cloud Close Date & Time	11 OCT 2020 23:59

FDA-CBER-2022-1614-0808261

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 OCT 2020 06:30:58
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

FDA-CBER-2022-1614-0808262

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 OCT 2020 05:32:02
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

FDA-CBER-2022-1614-0808263

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 12:02:11
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

FDA-CBER-2022-1614-0808264

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 00:01:45
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

FDA-CBER-2022-1614-0808265

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 NOV 2020 07:43:06
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

FDA-CBER-2022-1614-0808266

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46

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 ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 09:23:13
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

FDA-CBER-2022-1614-0808267

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 12:47:27
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

FDA-CBER-2022-1614-0808268

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 12:08:33
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

FDA-CBER-2022-1614-0808269

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 05:44:30
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

FDA-CBER-2022-1614-0808270

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 12:06:07
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

FDA-CBER-2022-1614-0808271

US3522042
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808272

US3522042
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **21 Feb 2021 21:15:47**
Generated On: 11 Aug 2021 22:50:46

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

FDA-CBER-2022-1614-0808273

US3522042
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **21 Feb 2021 21:15:47**
Generated On: 11 Aug 2021 22:50:46

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0808274

US3522042
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **21 Feb 2021 21:15:47**
Generated On: 11 Aug 2021 22:50:46

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	3 DEC 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	NO ONGOING OR NEW AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE

FDA-CBER-2022-1614-0808275

US3522042
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **19 Mar 2021 17:59:14**
Generated On: 11 Aug 2021 22:50:46

Is the participant continuing to the next visit?	Yes ☐ No ■
Continuing Flag	

FDA-CBER-2022-1614-0808276

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: COVID-19 Contact
Data signed: (b) (4) **21 Feb 2021 21:15:23**
Generated On: 11 Aug 2021 22:50:46

Date of Contact	24 AUG 2020
Time of Contact	09:00
Date and Time of Contact (derived)	24 AUG 2020 09:00
Type of Contact	Clinic Visit - Scheduled ☐ Clinical Visit - Unscheduled ☐ Safety Call ■ Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ■ No ☐

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808278

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	22 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	100.9 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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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 ☐

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	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	25 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.1 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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

	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 ☐

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

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808286

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	26 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.9 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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808290

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	27 AUG 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	97.1 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 ☐

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808294

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	28 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.5 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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808298

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	29 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.9 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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808302

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	30 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98 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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808306

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	31 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97 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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	1 SEP 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98.3 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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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 ☐

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	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	2 SEP 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.9 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 ☐

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808318

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	3 SEP 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98.2 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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	4 SEP 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	97.9 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 ☐

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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

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	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	5 SEP 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	98.1 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 ☐

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808330

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	6 SEP 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	97.9 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 ☐

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808334

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	7 SEP 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.8 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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808338

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	08 SEP 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.8 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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808342

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	09 SEP 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.1 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 ☐

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808346

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	10 SEP 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.6 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 ☐

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808350

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	11 SEP 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	97.9 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 ☐

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808354

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	12 SEP 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	97.9 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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808358

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	13 SEP 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.3 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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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 ☐

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	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	23 AUG 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	99 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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

	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 ☐

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

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

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-2022-1614-0808366

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	24 AUG 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	98 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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Data signed: (b) (4) **30 Apr 2021 18:22:46**
Generated On: 11 Aug 2021 22:50:46

	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 ☐

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **21 Feb 2021 21:15:23**
Generated On: 11 Aug 2021 22:50:46

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

Did the subject have Respiratory Rates ≥ 30 per Minute?	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
Respiratory Rate	
Did the subject have Heart Rate ≥ 125 beats per minute	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
Heart Rate	
Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
Oxygen Saturation	
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
PaO2	
Did the subject have Respiratory failure?	Yes ☐ No ■
Start Date	
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?	Yes ☐ No ■
Start Date	

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

Ventilator Support:	
High-Flow Oxygen?	Yes ☐ No ☐
Start Date	
End Date	
Non-Invasive Ventilation?	Yes ☐ No ☐
Start Date	
End Date	
Mechanical Ventilation?	Yes ☐ No ☐
Start Date	
End Date	
ECMO?	Yes ☐ No ☐
Start Date	
End Date	
Evidence of Shock:	
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg	Yes ☐ No ■
Start Date	
End Date	
Evidence of Shock Requires Vasopressors	Yes ☐ No ☐
Start Date	
End Date	
Acute Renal Dysfunction?	Yes ☐ No ☐
Start Date	

Hepatic Dysfunction?	Yes ☐ No ☐
Start Date	
Neurologic Dysfunction?	Yes ☐ No ☐
Start Date	
Evidence of Pneumonia:	
Clinical Evidence	Yes ☐ No ■
Date of Assessment	
Radiographical Evidence	Yes ☐ No ☐
Date of Assessment	

Admission to an intensive care unit due to SARS-CoV-2	Yes ☐ No ■
Start Date	
End Date	

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **09 Mar 2021 15:34:36**
Generated On: 11 Aug 2021 22:50:46

Generate Next COVID-19 Assessment	Yes ☐ No ■

FDA-CBER-2022-1614-0808374

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection
Data signed: (b) (4) **21 Feb 2021 21:15:24**
Generated On: 11 Aug 2021 22:50:46

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	26 AUG 2020
Day 5	Yes	28 AUG 2020
Day 7	Yes	30 AUG 2020
Day 9	Yes	1 SEP 2020
Day 14	Yes	06 SEP 2020
Day 21	Yes	13 SEP 2020
Day 28	Yes	21 SEP 2020

FDA-CBER-2022-1614-0808375

US3522042
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **21 Feb 2021 21:15:24**
Generated On: 11 Aug 2021 22:50:46

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD1

FDA-CBER-2022-1614-0808376

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Data signed: (b) (4) **21 Feb 2021 21:15:47**
Generated On: 11 Aug 2021 22:50:46

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	24 AUG 2020
Time of assessment *(00:00-23:59)*	16:05 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 16:05
Height *(xxx.x)*	67 in
Weight *(xxx.x)*	178.2 lb
Temperature *(xxx.x)*	97.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	93 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0808377

US3522042
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **21 Feb 2021 21:15:24**
Generated On: 11 Aug 2021 22:50:46

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	24 AUG 2020

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

FDA-CBER-2022-1614-0808378

US3522042
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **21 Feb 2021 21:15:24**
Generated On: 11 Aug 2021 22:50:46

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	24 AUG 2020

FDA-CBER-2022-1614-0808379

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Data signed: (b) (4) **21 Feb 2021 21:15:23**
Generated On: 11 Aug 2021 22:50:46

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD28

FDA-CBER-2022-1614-0808380

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Data signed: (b) (4) **21 Feb 2021 21:15:23**
Generated On: 11 Aug 2021 22:50:46

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	21 SEP 2020
Time of assessment *(00:00-23:59)*	11:32 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:32
Height *(xxx.x)*	ND - Not Done
Weight *(xxx.x)*	ND - Not Done
Temperature *(xxx.x)*	97.8 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	55 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	93 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0808381

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Data signed: (b) (4) **21 Feb 2021 21:15:23**
Generated On: 11 Aug 2021 22:50:46

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	21 SEP 2020

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

FDA-CBER-2022-1614-0808382

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **21 Feb 2021 21:15:23**
Generated On: 11 Aug 2021 22:50:46

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	21 SEP 2020

FDA-CBER-2022-1614-0808383

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **21 Feb 2021 21:15:47**
Generated On: 11 Aug 2021 22:50:46

Was this visit performed?	Yes ☐ No ■
Visit date (dd MMM yyyy)	
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☐
Folder OID	UNBLND_DECIDE

FDA-CBER-2022-1614-0808384

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **12 Mar 2021 15:13:37**
Generated On: 11 Aug 2021 22:50:46

Date of updated informed consent *(dd MMM yyyy)*	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	True
Was the participant unblinded?	Yes ■ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ■ Amendment 6 or later ☐
Date of unblinding *(dd MMM yyyy)*	24 DEC 2020
Participant randomization assignment	mRNA-1273 ☐ Placebo ■
Actual Dose 1	mRNA-1273 ☐ Placebo ■ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ■ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ■
Placebo Only Flag	1
Continuing with mRNA-1273	

FDA-CBER-2022-1614-0808385

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **21 Feb 2021 21:15:47**
Generated On: 11 Aug 2021 22:50:46

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

FDA-CBER-2022-1614-0808386

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **21 Feb 2021 21:15:47**
Generated On: 11 Aug 2021 22:50:46

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

FDA-CBER-2022-1614-0808387

US3522042
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **21 Feb 2021 21:15:23**
Generated On: 11 Aug 2021 22:50:46

Did the participant experience any adverse events?	Yes ■ No ☐

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-0808388

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **21 Feb 2021 21:15:22**
Generated On: 11 Aug 2021 22:50:46

AEID	USA-US131-2020-MRNA-1273-P30 1000001
Adverse event	SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ■ No ☐
Start date *(dd MMM yyyy)*	22 AUG 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	30 AUG 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

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

Narrative

	PARTICIPANT CONTACTED US ON 8/24/2020 TO TELL US HE HAD SYMPTOMS AND TESTED POSITIVE FOR COVID-19 ON 8/22/2020 AFTER PREVIOUSLY ATTENDING A FAMILY GATHERING WHICH LATER HAD MULTIPLE MEMBERS TEST POSITIVE. INITIAL SYMPOTOMS ON THE 22ND WAS 100.9 F, MILD CHILLS, MILD HEADACHE, MODERATE LOSS OF SMELL, MILD COUGH, MILD BODY ACHES. NO MEDS TAKEN. 23RD TEMP WAS 99, TOOK TYLENOL 650 MG ONCE, 24 TEMP 98, MILD BODY ACHES, TYLENOL 650 MG ONCE IN MORNING. IN AFTERNOON WENT TO ILLNESS VISIT AT CLINIC SO DAY 1 FOR STUDY OBSERVATION IS DAY 3 OF INFECTION. ILLNESS VISIT D1 SWAB SENT TO VIRACOR AND TESTED POSITIVE. DAY 7 SALIVA FROM 30 AUG 2020 TESTED NEGATIVE
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **21 Feb 2021 21:15:23**
Generated On: 11 Aug 2021 22:50:46

Were any prior/concomitant medications and/or vaccinations taken?	Yes ■ No ☐

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

FDA-CBER-2022-1614-0808392

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **21 Feb 2021 21:15:23**
Generated On: 11 Aug 2021 22:50:46

Name of Medication	HYDROCHLOROTHIAZIDE
Prophylaxis	Yes ○ No ●
Indication	HYPERTENSION
Dose per administration	12.5
Dose unit	mg ● ug ○ mL ○ g ○ IU ○ tablet ○ capsule ○ puff ○ Other ○
If dose unit is Other, specify	
Frequency	once daily ● twice daily ○ three times daily ○ four times daily ○ every other day ○ every week ○ every month ○ as needed ○ once ○ unknown ○ other ○
If frequency is Other, specify	
Route of administration	Oral ● Topical ○ Subcutaneous ○ Transdermal ○ Intraocular ○

FDA-CBER-2022-1614-0808393

	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 2012
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 ■

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **21 Feb 2021 21:15:23**
Generated On: 11 Aug 2021 22:50:46

Name of Medication	LORATADINE
Prophylaxis	Yes ○ No ●
Indication	SEASONAL ALLERGIES
Dose per administration	10
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 ○

FDA-CBER-2022-1614-0808395

	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)*	
Start date completely unknown	True
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 ■

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **21 Feb 2021 21:15:23**
Generated On: 11 Aug 2021 22:50:46

Name of Medication	TYLENOL
Prophylaxis	Yes No ■
Indication	SYMPTOMATIC COVID-19
Dose per administration	650
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)*	23 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	24 AUG 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 ■

US3522042
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **21 Feb 2021 21:15:23**
Generated On: 11 Aug 2021 22:50:46

Were any concomitant procedures performed?	Yes ☐ No ■

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-0808399

US3522042
Folder: End of Study (1)
Form: Dosing Discontinuation
Data signed: (b) (4) **21 Feb 2021 21:15:24**
Generated On: 11 Aug 2021 22:50:46

Date of dosing discontinuation (dd MMM yyyy)	22 AUG 2020
Primary reason for dosing discontinuation	AE (specify) ☐ SAE (specify) ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Due to SARS-COV-2 ■ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	

FDA-CBER-2022-1614-0808400

US3522042
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **21 Feb 2021 21:15:24**
Generated On: 11 Aug 2021 22:50:46

Date of study discontinuation/completion *(dd MMM yyyy)*	24 DEC 2020
Reason for discontinuation	AE (specify) ☐ SAE (specify) ☐ Complete ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Other ■
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	WITHDREW TO RECEIVE EUA APPROVED COVID-19 VACCINE
If reason for discontinuation is Death, main cause of death	Adverse event ☐ Unknown ☐ Other ☐
If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	
Was autopsy performed?	Yes ☐ No ☐ Unknown ☐

FDA-CBER-2022-1614-0808401

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Data signed: (b) (4) **21 Feb 2021 21:15:47**
Generated On: 11 Aug 2021 22:50:46

SAEID	USA-US131-2020-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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

FDA-CBER-2022-1614-0808402

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form (1)
Data signed: (b) (4) **21 Feb 2021 21:15:47**
Generated On: 11 Aug 2021 22:50:46

SAEID	USA-US131-2020-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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	24/AUG/2020 12:23
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

FDA-CBER-2022-1614-0808403

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form (2)
Data signed: (b) (4) **21 Feb 2021 21:15:47**
Generated On: 11 Aug 2021 22:50:46

SAEID	USA-US131-2020-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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	31/AUG/2020 08:52
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

FDA-CBER-2022-1614-0808404

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form (3)
Data signed: (b) (4) **21 Feb 2021 21:15:47**
Generated On: 11 Aug 2021 22:50:46

SAEID	USA-US131-2020-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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/SEP/2020 18:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-0808405

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form (4)
Data signed: (b) (4) **21 Feb 2021 21:15:47**
Generated On: 11 Aug 2021 22:50:46

SAEID	USA-US131-2020-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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/SEP/2020 17:13
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

US3522042 (Prod: Henry Ford Health System)

US3522042
Form: Participant Creation
Generated On: 11 Aug 2021 22:50:46
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'US3522042'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:24:17

FDA-CBER-2022-1614-0808408

US3522042
Form: Participant Creation
Generated On: 11 Aug 2021 22:50:46

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22

FDA-CBER-2022-1614-0808409

US3522042
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:34:38

FDA-CBER-2022-1614-0808410

US3522042
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:24:18

FDA-CBER-2022-1614-0808411

US3522042
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Clinic (Clinic)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:34:38

FDA-CBER-2022-1614-0808412

US3522042
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'SCRN'	System	07 Aug 2020 13:34:38

FDA-CBER-2022-1614-0808413

US3522042
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:50:46
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered (b) (6) 1985'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:24:19

FDA-CBER-2022-1614-0808414

US3522042
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:50:46
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '34'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

FDA-CBER-2022-1614-0808415

US3522042
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:50:46
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'YEARS'	System	07 Aug 2020 13:35:23

FDA-CBER-2022-1614-0808416

US3522042
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:50:46
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '34'	System	07 Aug 2020 13:35:47

FDA-CBER-2022-1614-0808417

US3522042
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:50:46
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Male (M)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

FDA-CBER-2022-1614-0808418

US3522042
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:50:46
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

FDA-CBER-2022-1614-0808419

US3522042
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:50:46
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '1'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

FDA-CBER-2022-1614-0808420

US3522042
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:50:46
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

FDA-CBER-2022-1614-0808421

US3522042
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:50:46
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

FDA-CBER-2022-1614-0808422

US3522042
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:50:46
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

FDA-CBER-2022-1614-0808423

US3522042
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:50:46
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

FDA-CBER-2022-1614-0808424

US3522042
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:50:46
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

FDA-CBER-2022-1614-0808425

US3522042
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:50:46
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

FDA-CBER-2022-1614-0808426

US3522042
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:50:46
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

FDA-CBER-2022-1614-0808427

US3522042
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:50:46
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

FDA-CBER-2022-1614-0808428

US3522042
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:50:46
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User closed query 'Per CDM: Per CCG, Date should be entered in (dd MMM yyyy) format. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:39:19
User entered '07 Aug 2020' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 15:16:26
Query 'Per CDM: Per CCG, Date should be entered in (dd MMM yyyy) format. Please review and update accordingly.' answered with 'Please fix medidata. The auto calendar button was used and formats the date as d MMM yyyy. Don't provide a calendar option if it does not format the way you want.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 15:16:20
User opened query 'Per CDM: Per CCG, Date should be entered in (dd MMM yyyy) format. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:12:40
User entered '7 Aug 2020'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:47

FDA-CBER-2022-1614-0808429

US3522042
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:50:46
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'Aug 2020'	System	07 Aug 2020 13:35:47

FDA-CBER-2022-1614-0808430

US3522042
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:50:46
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '2020'	System	07 Aug 2020 13:35:47

FDA-CBER-2022-1614-0808431

US3522042
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:50:46
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Amendment 1 (1)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:47

FDA-CBER-2022-1614-0808432

US3522042
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:50:46
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:47

FDA-CBER-2022-1614-0808433

US3522042
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:50:46
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:47

FDA-CBER-2022-1614-0808434

US3522042
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:50:46
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:47

FDA-CBER-2022-1614-0808435

US3522042
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:50:46
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:47

FDA-CBER-2022-1614-0808436

US3522042
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:50:46
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:24:18

FDA-CBER-2022-1614-0808437

US3522042
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:50:46
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	07 Aug 2020 13:35:53

FDA-CBER-2022-1614-0808438

US3522042
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 11 Aug 2021 22:50:46
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:53

FDA-CBER-2022-1614-0808439

US3522042
Folder: Screening
Form: Medical History Summary
Generated On: 11 Aug 2021 22:50:46
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:06:18
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:44:40

FDA-CBER-2022-1614-0808440

US3522042
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:50:46
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
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 Aug 2020 13:08:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 13:08:43
Data point term sent to Coder	System	28 Aug 2020 13:07:12
User entered 'Hypertension'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:06:27

FDA-CBER-2022-1614-0808441

US3522042
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:50:46
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:06:27

FDA-CBER-2022-1614-0808442

US3522042
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:50:46
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '1'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:06:27

FDA-CBER-2022-1614-0808443

US3522042
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:50:46
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:06:27

FDA-CBER-2022-1614-0808444

US3522042
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:50:46
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:06:27

FDA-CBER-2022-1614-0808445

US3522042
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:50:46
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '0'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:06:27

FDA-CBER-2022-1614-0808446

US3522042
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:50:46
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	28 Aug 2020 13:06:27

FDA-CBER-2022-1614-0808447

US3522042
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:50:46
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	28 Aug 2020 13:06:27

FDA-CBER-2022-1614-0808448

US3522042
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:50:46
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	28 Aug 2020 13:06:27

FDA-CBER-2022-1614-0808449

US3522042
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:50:46
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	28 Aug 2020 13:06:27

FDA-CBER-2022-1614-0808450

US3522042
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:50:46
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 18:40:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 18:40:47
Data point term sent to Coder	System	14 Sep 2020 18:39:53
User entered 'Seasonal Allergies'	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:39:48

FDA-CBER-2022-1614-0808451

US3522042
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:50:46
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:39:48

FDA-CBER-2022-1614-0808452

US3522042
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:50:46
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '1'	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:39:48

FDA-CBER-2022-1614-0808453

US3522042
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:50:46
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:39:48

FDA-CBER-2022-1614-0808454

US3522042
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:50:46
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:39:48

FDA-CBER-2022-1614-0808455

US3522042
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:50:46
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '0'	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:39:48

FDA-CBER-2022-1614-0808456

US3522042
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:50:46
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	14 Sep 2020 18:39:48

FDA-CBER-2022-1614-0808457

US3522042
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:50:46
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	14 Sep 2020 18:39:48

FDA-CBER-2022-1614-0808458

US3522042
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:50:46
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	14 Sep 2020 18:39:48

FDA-CBER-2022-1614-0808459

US3522042
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:50:46
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	14 Sep 2020 18:39:48

FDA-CBER-2022-1614-0808460

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:59:19

FDA-CBER-2022-1614-0808461

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User closed query 'Per CDM: Per CCG, Date of assessment should be recorded in (dd-MMM-yyyy) format. Please review and update it accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:39:39
Query 'Per CDM: Per CCG, Date of assessment should be recorded in (dd-MMM-yyyy) format. Please review and update it accordingly.' answered with 'Please fix medidata. The auto calendar button was used and formats the date as d MMM yyyy. Don't provide a calendar option if it does not format the way you want.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 15:20:06
User entered '07 Aug 2020' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 15:20:02
User opened query 'Per CDM: Per CCG, Date of assessment should be recorded in (dd-MMM-yyyy) format. Please review and update it accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:07:42
User entered '7 Aug 2020'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:59:19

FDA-CBER-2022-1614-0808462

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '09:55'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:59:19

FDA-CBER-2022-1614-0808463

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '07 Aug 2020 09:55'	System	06 Nov 2020 15:20:02
User entered '7 Aug 2020 09:55'	System	07 Aug 2020 13:59:19

FDA-CBER-2022-1614-0808464

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '67' in	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:59:19
DataPoint set to visible.	System	07 Aug 2020 13:35:53

FDA-CBER-2022-1614-0808465

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '178.2' lb	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:59:19
DataPoint set to visible.	System	07 Aug 2020 13:35:53

FDA-CBER-2022-1614-0808466

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
Amendment Manager: User entered '27.96842'	System	16 Sep 2020 23:46:54
User entered '28.0'	System	07 Aug 2020 13:59:19
DataPoint set to visible.	System	07 Aug 2020 13:35:53

FDA-CBER-2022-1614-0808467

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'kg/m2'	System	07 Aug 2020 13:59:19
DataPoint set to visible.	System	07 Aug 2020 13:35:53

FDA-CBER-2022-1614-0808468

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 14:26:24
User entered '98.3' F	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:59:19

FDA-CBER-2022-1614-0808469

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User closed query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 14:38:04
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 19:33:45
Query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' answered with 'done' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 19:33:41
User opened query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 04:33:03
User entered 'Oral (Oral)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:59:19

FDA-CBER-2022-1614-0808470

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:59:19

FDA-CBER-2022-1614-0808471

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 14:26:24
User entered '65'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:59:19

FDA-CBER-2022-1614-0808472

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'bpm'	System	07 Aug 2020 13:59:19

FDA-CBER-2022-1614-0808473

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 14:26:24
User entered '14'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:59:19

FDA-CBER-2022-1614-0808474

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'breaths/min'	System	07 Aug 2020 13:59:19

FDA-CBER-2022-1614-0808475

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 14:26:24
User entered '128'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:59:19

FDA-CBER-2022-1614-0808476

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'mmHg'	System	07 Aug 2020 13:59:19

FDA-CBER-2022-1614-0808477

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 14:26:24
User entered '91'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:59:19

FDA-CBER-2022-1614-0808478

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'mmHg'	System	07 Aug 2020 13:59:19

FDA-CBER-2022-1614-0808479

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22

FDA-CBER-2022-1614-0808480

US3522042
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22

FDA-CBER-2022-1614-0808481

US3522042
Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 22:50:46
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:03:21

US3522042
Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 22:50:46
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	27 Aug 2020 13:47:05
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 19:23:38
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 19:23:38
User entered '07 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:23:38
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 15:31:21
User entered '7 Aug 2020'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:03:21

FDA-CBER-2022-1614-0808483

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808484

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808485

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
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)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808486

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
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)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808487

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808488

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
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)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808489

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
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)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808490

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
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)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808491

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
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)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808492

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
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)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808493

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
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)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808495

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808496

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808497

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808498

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46

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)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808499

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
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)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808500

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
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)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '1'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808502

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808503

US3522042
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:50:46
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

FDA-CBER-2022-1614-0808504

US3522042
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:06:05

FDA-CBER-2022-1614-0808505

US3522042
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '07 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:23:26
User entered '7 Aug 2020'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:06:05

FDA-CBER-2022-1614-0808506

US3522042
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Clinic (Clinic)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:06:05

US3522042
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'VISIT1'	System	07 Aug 2020 14:06:05

FDA-CBER-2022-1614-0808508

US3522042
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:50:46
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:29:07

FDA-CBER-2022-1614-0808509

US3522042
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:50:46
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:47:06
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:47:05
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 13:29:07
User entered '101710' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:29:07

FDA-CBER-2022-1614-0808510

US3522042
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:50:46
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:29:07

FDA-CBER-2022-1614-0808511

US3522042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:50:46

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)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:06:14

US3522042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:50:46

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)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:06:14

US3522042
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:50:46
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:06:14

FDA-CBER-2022-1614-0808514

US3522042
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:50:46
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:06:14

FDA-CBER-2022-1614-0808515

US3522042
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:50:46
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:06:14

FDA-CBER-2022-1614-0808516

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:50:46
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered missing code ND - Not Done; reason for change Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 14:25:56
User entered '67' in reason for change: Per Query Resolution	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:52
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808517

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:50:46
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered missing code ND - Not Done; reason for change Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 14:25:56
User entered '178.2' lb reason for change: Per Query Resolution	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:52
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808518

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:50:46
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered missing code ND - Not Done; reason for change Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 14:25:56
User entered '67' in reason for change: Per Query Resolution	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:52
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808519

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:50:46
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered missing code ND - Not Done; reason for change Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 14:25:56
User entered '178.2' lb reason for change: Per Query Resolution	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:52
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808520

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User accepted default value 'Pre-Dose (PREDOSE)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808521

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 15:27:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Aug 2020 15:27:52
User entered 'Yes (Y)' reason for change: Per Query Resolution	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:52
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 15:27:16
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808522

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '7 Aug 2020'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808523

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '09:55'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808524

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '7 Aug 2020 09:55'	System	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808525

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '98.3' F	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808526

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Oral (Oral)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808527

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808528

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '65'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808529

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'bpm'	System	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808530

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '14'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808531

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'breaths/min'	System	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808532

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '128'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808533

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'mmHg'	System	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808534

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '91'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808535

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'mmHg'	System	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808536

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:50:46
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered missing code ND - Not Done; reason for change Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 14:25:56
User entered '67' in reason for change: Per Query Resolution	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:52
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808537

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:50:46
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered missing code ND - Not Done; reason for change Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 14:25:56
User entered '178.2' lb reason for change: Per Query Resolution	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:52
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808538

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User accepted default value 'Post-Dose (POSTDOSE)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808539

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 15:27:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Aug 2020 15:27:52
User entered 'Yes (Y)' reason for change: Per Query Resolution	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:52
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 15:27:16
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808540

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '7 Aug 2020'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808541

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User closed query 'Per CDM: the treatment time on the Exposure CRF is 11:00. The Vital Signs Post Dose Time of Assessment is 11:20. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 07:59:50
Query 'Per CDM: the treatment time on the Exposure CRF is 11:00. The Vital Signs Post Dose Time of Assessment is 11:20. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' answered with 'Exposure was 10:50 per source. Fixed' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	23 Aug 2020 16:26:52
User opened query 'Per CDM: the treatment time on the Exposure CRF is 11:00. The Vital Signs Post Dose Time of Assessment is 11:20. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 11:31:49
Query 'Per CDM: The treatment time on the Exposure CRF is 11:11. The Vital Signs Post Dose Time of Assessment is 11:20. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' canceled (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 11:31:07
User opened query 'Per CDM: The treatment time on the Exposure CRF is 11:11. The Vital Signs Post Dose Time of Assessment is 11:20. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 11:30:40
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:29:54

FDA-CBER-2022-1614-0808542

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Reviewed' (Site from System).	mayur ramesh (b) (4) (b) (4)	11 Aug 2020 04:56:04
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	07 Aug 2020 15:27:16
User entered '11:20'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808543

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '7 Aug 2020 11:20'	System	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808544

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '97.9' F	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808545

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Oral (Oral)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808546

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808547

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '54'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808548

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'bpm'	System	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808549

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '16'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808550

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'breaths/min'	System	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808551

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '125'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808552

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'mmHg'	System	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808553

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '90'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808554

US3522042
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'mmHg'	System	07 Aug 2020 15:27:16

FDA-CBER-2022-1614-0808555

US3522042
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 22:50:46
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	17 Aug 2020 15:41:27
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:06:27

FDA-CBER-2022-1614-0808556

US3522042
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 22:50:46
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	17 Aug 2020 15:41:27
User entered '7 Aug 2020'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:06:27

FDA-CBER-2022-1614-0808557

US3522042
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808558

US3522042
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808559

US3522042
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:50:46

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)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808560

US3522042
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808561

US3522042
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '7 Aug 2020'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808562

US3522042
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '10:50' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	23 Aug 2020 16:24:42
User entered '11:00' reason for change: Data Entry Error	Marcus Zervos (b) (4) (b) (4)	07 Aug 2020 15:03:58
User entered '10:50'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808563

US3522042
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '7 Aug 2020 10:50'	System	23 Aug 2020 16:24:42
User entered '7 Aug 2020 11:00'	System	07 Aug 2020 15:03:58
User entered '7 Aug 2020 10:50'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808564

US3522042
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Left Arm (LEFT ARM)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808565

US3522042
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'ONCE'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808566

US3522042
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808567

US3522042
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:50:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:10

FDA-CBER-2022-1614-0808568

US3522042
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:50:46
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '7 Aug 2020'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:10

FDA-CBER-2022-1614-0808569

US3522042
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:50:46
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '09:47'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:10

FDA-CBER-2022-1614-0808570

US3522042
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:50:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '7 Aug 2020 09:47'	System	07 Aug 2020 14:01:10

FDA-CBER-2022-1614-0808571

US3522042
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 11 Aug 2021 22:50:46
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '7 Aug 2020'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:56

FDA-CBER-2022-1614-0808572

US3522042
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:50:46
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:56

FDA-CBER-2022-1614-0808573

US3522042
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:50:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:56

US3522042
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:50:46
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '09:35'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:56

FDA-CBER-2022-1614-0808575

US3522042
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:50:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '7 Aug 2020 09:35'	System	07 Aug 2020 14:01:56

FDA-CBER-2022-1614-0808576

US3522042
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:50:46
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:56

FDA-CBER-2022-1614-0808577

US3522042
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:50:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:56

FDA-CBER-2022-1614-0808578

US3522042
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:50:46
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:56

FDA-CBER-2022-1614-0808579

US3522042
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:50:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	07 Aug 2020 14:01:56

FDA-CBER-2022-1614-0808580

US3522042
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:34:57

FDA-CBER-2022-1614-0808581

US3522042
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	07 Aug 2020 15:34:57

FDA-CBER-2022-1614-0808582

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 14:57:26

(b

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US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:20:39', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '2f6bc591-6e7a-474c-9429-151abe97f802'	System	07 Aug 2020 15:20:58
User entered 'Yes (Y)'	System	07 Aug 2020 15:20:58

FDA-CBER-2022-1614-0808584

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:20:43', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '2f6bc591-6e7a-474c-9429-151abe97f802'	System	07 Aug 2020 15:20:58
User entered '97.9'	System	07 Aug 2020 15:20:58

FDA-CBER-2022-1614-0808585

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:20:47', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '2f6bc591-6e7a-474c-9429-151abe97f802'	System	07 Aug 2020 15:20:58
User entered 'No (N)'	System	07 Aug 2020 15:20:58

FDA-CBER-2022-1614-0808586

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:20:54', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '2f6bc591-6e7a-474c-9429-151abe97f802'	System	07 Aug 2020 15:20:58
User entered '07 Aug 2020 11:20'	System	07 Aug 2020 15:20:58

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
User entered '07 Aug 2020 11:20'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 11:10'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808588

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '07 Aug 2020 13:50'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 13:40'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808589

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808590

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:50:25', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '5f68918a-94fe-4797-93ec-0536b58e3a3e'	System	07 Aug 2020 18:50:41
User entered 'Yes (Y)'	System	07 Aug 2020 18:50:41

FDA-CBER-2022-1614-0808591

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:50:31', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '5f68918a-94fe-4797-93ec-0536b58e3a3e'	System	07 Aug 2020 18:50:41
User entered '97.8'	System	07 Aug 2020 18:50:41

FDA-CBER-2022-1614-0808592

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:50:34', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '5f68918a-94fe-4797-93ec-0536b58e3a3e'	System	07 Aug 2020 18:50:41
User entered 'No (N)'	System	07 Aug 2020 18:50:41

FDA-CBER-2022-1614-0808593

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:50:36', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '5f68918a-94fe-4797-93ec-0536b58e3a3e'	System	07 Aug 2020 18:50:41
User entered '07 Aug 2020 14:50'	System	07 Aug 2020 18:50:41

FDA-CBER-2022-1614-0808594

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '07 Aug 2020 14:45'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 14:35'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808595

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808596

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 2'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808597

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:50:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:04:05', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '935eb1ef-cefe-433a-801a-7f2d191fea95'	System	08 Aug 2020 16:04:14
User entered 'Yes (Y)'	System	08 Aug 2020 16:04:14

FDA-CBER-2022-1614-0808598

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:50:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:04:07', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '935eb1ef-cefe-433a-801a-7f2d191fea95'	System	08 Aug 2020 16:04:14
User entered '97.0'	System	08 Aug 2020 16:04:14

FDA-CBER-2022-1614-0808599

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:50:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:04:09', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '935eb1ef-cefe-433a-801a-7f2d191fea95'	System	08 Aug 2020 16:04:14
User entered 'No (N)'	System	08 Aug 2020 16:04:14

FDA-CBER-2022-1614-0808600

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:50:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:04:11', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '935eb1ef-cefe-433a-801a-7f2d191fea95'	System	08 Aug 2020 16:04:14
User entered '08 Aug 2020 12:04'	System	08 Aug 2020 16:04:14

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808602

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808603

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 3'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808604

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:50:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:40', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '06ce6e6e-fc93-4bb2-8ebe-6b3cf48dd9d0'	System	09 Aug 2020 18:46:07
User entered 'Yes (Y)'	System	09 Aug 2020 18:46:07

FDA-CBER-2022-1614-0808605

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:50:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:53', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '06ce6e6e-fc93-4bb2-8ebe-6b3cf48dd9d0'	System	09 Aug 2020 18:46:07
User entered '97.5'	System	09 Aug 2020 18:46:07

FDA-CBER-2022-1614-0808606

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:50:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:56', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '06ce6e6e-fc93-4bb2-8ebe-6b3cf48dd9d0'	System	09 Aug 2020 18:46:07
User entered 'No (N)'	System	09 Aug 2020 18:46:07

FDA-CBER-2022-1614-0808607

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:50:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:46:02', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '06ce6e6e-fc93-4bb2-8ebe-6b3cf48dd9d0'	System	09 Aug 2020 18:46:07
User entered '09 Aug 2020 14:46'	System	09 Aug 2020 18:46:07

FDA-CBER-2022-1614-0808608

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808609

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808610

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 4'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808611

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:50:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:06:47', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '47e64f70-3d35-448c-9047-03ca90a3d73d'	System	10 Aug 2020 20:07:08
User entered 'Yes (Y)'	System	10 Aug 2020 20:07:08

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:50:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:06:50', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '47e64f70-3d35-448c-9047-03ca90a3d73d'	System	10 Aug 2020 20:07:08
User entered '96.8'	System	10 Aug 2020 20:07:08

FDA-CBER-2022-1614-0808613

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:50:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:01', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '47e64f70-3d35-448c-9047-03ca90a3d73d'	System	10 Aug 2020 20:07:08
User entered 'No (N)'	System	10 Aug 2020 20:07:08

FDA-CBER-2022-1614-0808614

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:50:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:05', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '47e64f70-3d35-448c-9047-03ca90a3d73d'	System	10 Aug 2020 20:07:08
User entered '10 Aug 2020 16:07'	System	10 Aug 2020 20:07:08

FDA-CBER-2022-1614-0808615

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808616

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808617

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 5'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808618

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:50:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:24:28', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'd3ffa73d-0b6a-458d-8727-4098f6f7b791'	System	11 Aug 2020 16:24:37
User entered 'Yes (Y)'	System	11 Aug 2020 16:24:37

FDA-CBER-2022-1614-0808619

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:50:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:24:31', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'd3ffa73d-0b6a-458d-8727-4098f6f7b791'	System	11 Aug 2020 16:24:37
User entered '97.1'	System	11 Aug 2020 16:24:37

FDA-CBER-2022-1614-0808620

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:50:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:24:32', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'd3ffa73d-0b6a-458d-8727-4098f6f7b791'	System	11 Aug 2020 16:24:37
User entered 'No (N)'	System	11 Aug 2020 16:24:37

FDA-CBER-2022-1614-0808621

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:50:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:24:34', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'd3ffa73d-0b6a-458d-8727-4098f6f7b791'	System	11 Aug 2020 16:24:37
User entered '11 Aug 2020 12:24'	System	11 Aug 2020 16:24:37

FDA-CBER-2022-1614-0808622

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808623

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808624

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 6'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808625

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:50:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:49:51', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e9293368-bdbc-45aa-9eb0-f0c897bbe2aa'	System	12 Aug 2020 17:49:59
User entered 'Yes (Y)'	System	12 Aug 2020 17:49:59

FDA-CBER-2022-1614-0808626

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:50:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:49:54', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e9293368-bdbc-45aa-9eb0-f0c897bbe2aa'	System	12 Aug 2020 17:49:59
User entered '97.9'	System	12 Aug 2020 17:49:59

FDA-CBER-2022-1614-0808627

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:50:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:49:56', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e9293368-bdbc-45aa-9eb0-f0c897bbe2aa'	System	12 Aug 2020 17:49:59
User entered 'No (N)'	System	12 Aug 2020 17:49:59

FDA-CBER-2022-1614-0808628

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:50:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:49:57', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e9293368-bdbc-45aa-9eb0-f0c897bbe2aa'	System	12 Aug 2020 17:49:59
User entered '12 Aug 2020 13:49'	System	12 Aug 2020 17:49:59

FDA-CBER-2022-1614-0808629

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808630

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808631

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 7'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808632

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:50:46
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:35', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'fc1347e4-6038-4152-862a-07a15cc65110'	System	13 Aug 2020 16:18:43
User entered 'Yes (Y)'	System	13 Aug 2020 16:18:43

FDA-CBER-2022-1614-0808633

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:50:46
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:38', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'fc1347e4-6038-4152-862a-07a15cc65110'	System	13 Aug 2020 16:18:43
User entered '97.6'	System	13 Aug 2020 16:18:43

FDA-CBER-2022-1614-0808634

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:50:46
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:40', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'fc1347e4-6038-4152-862a-07a15cc65110'	System	13 Aug 2020 16:18:43
User entered 'No (N)'	System	13 Aug 2020 16:18:43

FDA-CBER-2022-1614-0808635

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:50:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:41', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'fc1347e4-6038-4152-862a-07a15cc65110'	System	13 Aug 2020 16:18:43
User entered '13 Aug 2020 12:18'	System	13 Aug 2020 16:18:43

FDA-CBER-2022-1614-0808636

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808637

US3522042
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808638

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808639

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:20:58', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '37bc38f5-4516-4516-9a70-75f1030b7285'	System	07 Aug 2020 15:21:13
User entered 'None (1)'	System	07 Aug 2020 15:21:13

FDA-CBER-2022-1614-0808640

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:01', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '37bc38f5-4516-4516-9a70-75f1030b7285'	System	07 Aug 2020 15:21:13
User entered 'No (N)'	System	07 Aug 2020 15:21:13

FDA-CBER-2022-1614-0808641

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:03', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '37bc38f5-4516-4516-9a70-75f1030b7285'	System	07 Aug 2020 15:21:13
User entered 'No (N)'	System	07 Aug 2020 15:21:13

FDA-CBER-2022-1614-0808642

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:09', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '37bc38f5-4516-4516-9a70-75f1030b7285'	System	07 Aug 2020 15:21:13
User entered 'None (1)'	System	07 Aug 2020 15:21:13

FDA-CBER-2022-1614-0808643

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:11', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '37bc38f5-4516-4516-9a70-75f1030b7285'	System	07 Aug 2020 15:21:13
User entered '07 Aug 2020 11:21'	System	07 Aug 2020 15:21:13

FDA-CBER-2022-1614-0808644

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
User entered '07 Aug 2020 11:20'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 11:10'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808645

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
User entered '07 Aug 2020 13:50'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 13:40'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808646

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808647

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:22', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '73ed35ec-8719-4f5f-b235-8d54f2fd0037'	System	07 Aug 2020 18:45:38
User entered 'None (1)'	System	07 Aug 2020 18:45:38

FDA-CBER-2022-1614-0808648

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:24', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '73ed35ec-8719-4f5f-b235-8d54f2fd0037'	System	07 Aug 2020 18:45:38
User entered 'No (N)'	System	07 Aug 2020 18:45:38

FDA-CBER-2022-1614-0808649

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:25', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '73ed35ec-8719-4f5f-b235-8d54f2fd0037'	System	07 Aug 2020 18:45:38
User entered 'No (N)'	System	07 Aug 2020 18:45:38

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:32', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '73ed35ec-8719-4f5f-b235-8d54f2fd0037'	System	07 Aug 2020 18:45:38
User entered 'None (1)'	System	07 Aug 2020 18:45:38

FDA-CBER-2022-1614-0808651

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:34', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '73ed35ec-8719-4f5f-b235-8d54f2fd0037'	System	07 Aug 2020 18:45:38
User entered '07 Aug 2020 14:45'	System	07 Aug 2020 18:45:38

FDA-CBER-2022-1614-0808652

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '07 Aug 2020 14:45'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 14:35'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808653

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808654

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 2'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808655

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:50:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:29', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6dfdbe9f-beb1-4586-9cfa-48b63f5e5817'	System	08 Aug 2020 16:00:38
User entered 'None (1)'	System	08 Aug 2020 16:00:38

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:50:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:31', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6dfdbe9f-beb1-4586-9cfa-48b63f5e5817'	System	08 Aug 2020 16:00:38
User entered 'No (N)'	System	08 Aug 2020 16:00:38

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:50:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:32', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6dfdbe9f-beb1-4586-9cfa-48b63f5e5817'	System	08 Aug 2020 16:00:38
User entered 'No (N)'	System	08 Aug 2020 16:00:38

FDA-CBER-2022-1614-0808658

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:50:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:34', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6dfdbe9f-beb1-4586-9cfa-48b63f5e5817'	System	08 Aug 2020 16:00:38
User entered 'None (1)'	System	08 Aug 2020 16:00:38

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:50:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:37', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6dfdbe9f-beb1-4586-9cfa-48b63f5e5817'	System	08 Aug 2020 16:00:38
User entered '08 Aug 2020 12:00'	System	08 Aug 2020 16:00:38

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808661

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808662

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 3'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808663

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:50:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:21', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '7926e932-2b9e-4ec9-ac4e-6a17b7372212'	System	09 Aug 2020 18:45:36
User entered 'None (1)'	System	09 Aug 2020 18:45:36

FDA-CBER-2022-1614-0808664

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:50:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:23', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '7926e932-2b9e-4ec9-ac4e-6a17b7372212'	System	09 Aug 2020 18:45:36
User entered 'No (N)'	System	09 Aug 2020 18:45:36

FDA-CBER-2022-1614-0808665

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:50:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:26', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '7926e932-2b9e-4ec9-ac4e-6a17b7372212'	System	09 Aug 2020 18:45:36
User entered 'No (N)'	System	09 Aug 2020 18:45:36

FDA-CBER-2022-1614-0808666

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:50:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:28', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '7926e932-2b9e-4ec9-ac4e-6a17b7372212'	System	09 Aug 2020 18:45:36
User entered 'None (1)'	System	09 Aug 2020 18:45:36

FDA-CBER-2022-1614-0808667

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:50:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:31', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '7926e932-2b9e-4ec9-ac4e-6a17b7372212'	System	09 Aug 2020 18:45:36
User entered '09 Aug 2020 14:45'	System	09 Aug 2020 18:45:36

FDA-CBER-2022-1614-0808668

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808669

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808670

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 4'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808671

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:50:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:07', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'ed03ce1a-ce1d-499e-823c-3763103c3754'	System	10 Aug 2020 20:07:22
User entered 'None (1)'	System	10 Aug 2020 20:07:22

FDA-CBER-2022-1614-0808672

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:50:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:09', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'ed03ce1a-ce1d-499e-823c-3763103c3754'	System	10 Aug 2020 20:07:22
User entered 'No (N)'	System	10 Aug 2020 20:07:22

FDA-CBER-2022-1614-0808673

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:50:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:11', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'ed03ce1a-ce1d-499e-823c-3763103c3754'	System	10 Aug 2020 20:07:22
User entered 'No (N)'	System	10 Aug 2020 20:07:22

FDA-CBER-2022-1614-0808674

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:50:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:16', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'ed03ce1a-ce1d-499e-823c-3763103c3754'	System	10 Aug 2020 20:07:22
User entered 'None (1)'	System	10 Aug 2020 20:07:22

FDA-CBER-2022-1614-0808675

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:50:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:20', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'ed03ce1a-ce1d-499e-823c-3763103c3754'	System	10 Aug 2020 20:07:22
User entered '10 Aug 2020 16:07'	System	10 Aug 2020 20:07:22

FDA-CBER-2022-1614-0808676

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808677

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808678

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 5'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808679

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:50:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:22:27', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '4855852d-67c8-48fc-a383-1903e3152d25'	System	11 Aug 2020 16:22:40
User entered 'None (1)'	System	11 Aug 2020 16:22:40

FDA-CBER-2022-1614-0808680

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:50:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:22:28', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '4855852d-67c8-48fc-a383-1903e3152d25'	System	11 Aug 2020 16:22:40
User entered 'No (N)'	System	11 Aug 2020 16:22:40

FDA-CBER-2022-1614-0808681

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:50:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:22:30', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '4855852d-67c8-48fc-a383-1903e3152d25'	System	11 Aug 2020 16:22:40
User entered 'No (N)'	System	11 Aug 2020 16:22:40

FDA-CBER-2022-1614-0808682

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:50:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:22:32', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '4855852d-67c8-48fc-a383-1903e3152d25'	System	11 Aug 2020 16:22:40
User entered 'None (1)'	System	11 Aug 2020 16:22:40

FDA-CBER-2022-1614-0808683

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:50:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:22:37', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '4855852d-67c8-48fc-a383-1903e3152d25'	System	11 Aug 2020 16:22:40
User entered '11 Aug 2020 12:22'	System	11 Aug 2020 16:22:40

FDA-CBER-2022-1614-0808684

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808685

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808686

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 6'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808687

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:50:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:00', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '55827b53-9e07-4356-878c-6317f733ab34'	System	12 Aug 2020 17:50:10
User entered 'None (1)'	System	12 Aug 2020 17:50:10

FDA-CBER-2022-1614-0808688

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:50:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:01', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '55827b53-9e07-4356-878c-6317f733ab34'	System	12 Aug 2020 17:50:10
User entered 'No (N)'	System	12 Aug 2020 17:50:10

FDA-CBER-2022-1614-0808689

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:50:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:02', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '55827b53-9e07-4356-878c-6317f733ab34'	System	12 Aug 2020 17:50:10
User entered 'No (N)'	System	12 Aug 2020 17:50:10

FDA-CBER-2022-1614-0808690

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:50:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:04', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '55827b53-9e07-4356-878c-6317f733ab34'	System	12 Aug 2020 17:50:10
User entered 'None (1)'	System	12 Aug 2020 17:50:10

FDA-CBER-2022-1614-0808691

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:50:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:06', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '55827b53-9e07-4356-878c-6317f733ab34'	System	12 Aug 2020 17:50:10
User entered '12 Aug 2020 13:50'	System	12 Aug 2020 17:50:10

FDA-CBER-2022-1614-0808692

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808693

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808694

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 7'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808695

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:50:46
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:44', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e2b65a6b-f29f-47af-950b-78b25fa38921'	System	13 Aug 2020 16:18:51
User entered 'None (1)'	System	13 Aug 2020 16:18:51

FDA-CBER-2022-1614-0808696

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:50:46
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:45', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e2b65a6b-f29f-47af-950b-78b25fa38921'	System	13 Aug 2020 16:18:51
User entered 'No (N)'	System	13 Aug 2020 16:18:51

FDA-CBER-2022-1614-0808697

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:50:46
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:47', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e2b65a6b-f29f-47af-950b-78b25fa38921'	System	13 Aug 2020 16:18:51
User entered 'No (N)'	System	13 Aug 2020 16:18:51

FDA-CBER-2022-1614-0808698

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:50:46
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:48', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e2b65a6b-f29f-47af-950b-78b25fa38921'	System	13 Aug 2020 16:18:51
User entered 'None (1)'	System	13 Aug 2020 16:18:51

FDA-CBER-2022-1614-0808699

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:50:46
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:50', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e2b65a6b-f29f-47af-950b-78b25fa38921'	System	13 Aug 2020 16:18:51
User entered '13 Aug 2020 12:18'	System	13 Aug 2020 16:18:51

FDA-CBER-2022-1614-0808700

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808701

US3522042
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808702

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808703

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:15', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'abb5d09a-322e-4aad-b946-8fc535617fca'	System	07 Aug 2020 15:21:34
User entered 'None (0)'	System	07 Aug 2020 15:21:34

FDA-CBER-2022-1614-0808704

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:19', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'abb5d09a-322e-4aad-b946-8fc535617fca'	System	07 Aug 2020 15:21:34
User entered 'None (0)'	System	07 Aug 2020 15:21:34

FDA-CBER-2022-1614-0808705

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:21', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'abb5d09a-322e-4aad-b946-8fc535617fca'	System	07 Aug 2020 15:21:34
User entered 'None (0)'	System	07 Aug 2020 15:21:34

FDA-CBER-2022-1614-0808706

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:23', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'abb5d09a-322e-4aad-b946-8fc535617fca'	System	07 Aug 2020 15:21:34
User entered 'None (0)'	System	07 Aug 2020 15:21:34

FDA-CBER-2022-1614-0808707

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:24', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'abb5d09a-322e-4aad-b946-8fc535617fca'	System	07 Aug 2020 15:21:34
User entered 'None (0)'	System	07 Aug 2020 15:21:34

FDA-CBER-2022-1614-0808708

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:26', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'abb5d09a-322e-4aad-b946-8fc535617fca'	System	07 Aug 2020 15:21:34
User entered 'None (0)'	System	07 Aug 2020 15:21:34

FDA-CBER-2022-1614-0808709

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:30', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'abb5d09a-322e-4aad-b946-8fc535617fca'	System	07 Aug 2020 15:21:34
User entered 'No (N)'	System	07 Aug 2020 15:21:34

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:32', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'abb5d09a-322e-4aad-b946-8fc535617fca'	System	07 Aug 2020 15:21:34
User entered '07 Aug 2020 11:21'	System	07 Aug 2020 15:21:34

FDA-CBER-2022-1614-0808711

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
User entered '07 Aug 2020 11:20'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 11:10'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808712

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
User entered '07 Aug 2020 13:50'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 13:40'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808713

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808714

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:37', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '87ed26de-0444-4078-8ed9-e87ad7a48535'	System	07 Aug 2020 18:45:54
User entered 'None (0)'	System	07 Aug 2020 18:45:54

FDA-CBER-2022-1614-0808715

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:39', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '87ed26de-0444-4078-8ed9-e87ad7a48535'	System	07 Aug 2020 18:45:54
User entered 'None (0)'	System	07 Aug 2020 18:45:54

FDA-CBER-2022-1614-0808716

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:43', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '87ed26de-0444-4078-8ed9-e87ad7a48535'	System	07 Aug 2020 18:45:54
User entered 'No interference with activity (1)'	System	07 Aug 2020 18:45:54

FDA-CBER-2022-1614-0808717

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:45', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '87ed26de-0444-4078-8ed9-e87ad7a48535'	System	07 Aug 2020 18:45:54
User entered 'None (0)'	System	07 Aug 2020 18:45:54

FDA-CBER-2022-1614-0808718

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:46', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '87ed26de-0444-4078-8ed9-e87ad7a48535'	System	07 Aug 2020 18:45:54
User entered 'None (0)'	System	07 Aug 2020 18:45:54

FDA-CBER-2022-1614-0808719

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:48', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '87ed26de-0444-4078-8ed9-e87ad7a48535'	System	07 Aug 2020 18:45:54
User entered 'None (0)'	System	07 Aug 2020 18:45:54

FDA-CBER-2022-1614-0808720

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:51', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '87ed26de-0444-4078-8ed9-e87ad7a48535'	System	07 Aug 2020 18:45:54
User entered 'No (N)'	System	07 Aug 2020 18:45:54

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:53', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '87ed26de-0444-4078-8ed9-e87ad7a48535'	System	07 Aug 2020 18:45:54
User entered '07 Aug 2020 14:45'	System	07 Aug 2020 18:45:54

FDA-CBER-2022-1614-0808722

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
User entered '07 Aug 2020 14:45'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 14:35'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808723

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808724

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 2'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808725

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:50:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:39', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e684ada7-271d-496b-813e-dd3033730b91'	System	08 Aug 2020 16:00:55
User entered 'None (0)'	System	08 Aug 2020 16:00:55

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:50:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:41', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e684ada7-271d-496b-813e-dd3033730b91'	System	08 Aug 2020 16:00:55
User entered 'None (0)'	System	08 Aug 2020 16:00:55

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:50:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:42', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e684ada7-271d-496b-813e-dd3033730b91'	System	08 Aug 2020 16:00:55
User entered 'None (0)'	System	08 Aug 2020 16:00:55

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:50:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:44', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e684ada7-271d-496b-813e-dd3033730b91'	System	08 Aug 2020 16:00:55
User entered 'None (0)'	System	08 Aug 2020 16:00:55

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:50:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:45', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e684ada7-271d-496b-813e-dd3033730b91'	System	08 Aug 2020 16:00:55
User entered 'None (0)'	System	08 Aug 2020 16:00:55

FDA-CBER-2022-1614-0808730

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:50:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:46', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e684ada7-271d-496b-813e-dd3033730b91'	System	08 Aug 2020 16:00:55
User entered 'None (0)'	System	08 Aug 2020 16:00:55

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:50:46
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:48', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e684ada7-271d-496b-813e-dd3033730b91'	System	08 Aug 2020 16:00:55
User entered 'No (N)'	System	08 Aug 2020 16:00:55

FDA-CBER-2022-1614-0808732

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:50:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:53', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e684ada7-271d-496b-813e-dd3033730b91'	System	08 Aug 2020 16:00:55
User entered '08 Aug 2020 12:00'	System	08 Aug 2020 16:00:55

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808734

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808735

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 3'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808736

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:50:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:44:46', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '1b97e425-cd0f-411e-a0b7-255d5fe83b64'	System	09 Aug 2020 18:45:20
User entered 'None (0)'	System	09 Aug 2020 18:45:20

FDA-CBER-2022-1614-0808737

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:50:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:44:51', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '1b97e425-cd0f-411e-a0b7-255d5fe83b64'	System	09 Aug 2020 18:45:20
User entered 'None (0)'	System	09 Aug 2020 18:45:20

FDA-CBER-2022-1614-0808738

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:50:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:44:54', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '1b97e425-cd0f-411e-a0b7-255d5fe83b64'	System	09 Aug 2020 18:45:20
User entered 'None (0)'	System	09 Aug 2020 18:45:20

FDA-CBER-2022-1614-0808739

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:50:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:44:57', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '1b97e425-cd0f-411e-a0b7-255d5fe83b64'	System	09 Aug 2020 18:45:20
User entered 'None (0)'	System	09 Aug 2020 18:45:20

FDA-CBER-2022-1614-0808740

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:50:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:00', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '1b97e425-cd0f-411e-a0b7-255d5fe83b64'	System	09 Aug 2020 18:45:20
User entered 'None (0)'	System	09 Aug 2020 18:45:20

FDA-CBER-2022-1614-0808741

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:50:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:02', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '1b97e425-cd0f-411e-a0b7-255d5fe83b64'	System	09 Aug 2020 18:45:20
User entered 'None (0)'	System	09 Aug 2020 18:45:20

FDA-CBER-2022-1614-0808742

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:50:46
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:07', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '1b97e425-cd0f-411e-a0b7-255d5fe83b64'	System	09 Aug 2020 18:45:20
User entered 'No (N)'	System	09 Aug 2020 18:45:20

FDA-CBER-2022-1614-0808743

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:50:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:15', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '1b97e425-cd0f-411e-a0b7-255d5fe83b64'	System	09 Aug 2020 18:45:20
User entered '09 Aug 2020 14:45'	System	09 Aug 2020 18:45:20

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808745

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808746

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 4'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808747

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:50:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:23', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '76d6511d-ed8a-4b99-83a9-92c3313193c6'	System	10 Aug 2020 20:07:41
User entered 'None (0)'	System	10 Aug 2020 20:07:41

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:50:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:24', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '76d6511d-ed8a-4b99-83a9-92c3313193c6'	System	10 Aug 2020 20:07:41
User entered 'None (0)'	System	10 Aug 2020 20:07:41

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:50:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:28', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '76d6511d-ed8a-4b99-83a9-92c3313193c6'	System	10 Aug 2020 20:07:41
User entered 'None (0)'	System	10 Aug 2020 20:07:41

FDA-CBER-2022-1614-0808750

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:50:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:32', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '76d6511d-ed8a-4b99-83a9-92c3313193c6'	System	10 Aug 2020 20:07:41
User entered 'None (0)'	System	10 Aug 2020 20:07:41

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:50:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:34', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '76d6511d-ed8a-4b99-83a9-92c3313193c6'	System	10 Aug 2020 20:07:41
User entered 'None (0)'	System	10 Aug 2020 20:07:41

FDA-CBER-2022-1614-0808752

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:50:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:36', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '76d6511d-ed8a-4b99-83a9-92c3313193c6'	System	10 Aug 2020 20:07:41
User entered 'None (0)'	System	10 Aug 2020 20:07:41

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:50:46
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:38', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '76d6511d-ed8a-4b99-83a9-92c3313193c6'	System	10 Aug 2020 20:07:41
User entered 'No (N)'	System	10 Aug 2020 20:07:41

FDA-CBER-2022-1614-0808754

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:50:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:39', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '76d6511d-ed8a-4b99-83a9-92c3313193c6'	System	10 Aug 2020 20:07:41
User entered '10 Aug 2020 16:07'	System	10 Aug 2020 20:07:41

FDA-CBER-2022-1614-0808755

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808756

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808757

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 5'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808758

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:50:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:23:19', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '942c3133-8a06-4129-a41d-215cd0fd9c3e'	System	11 Aug 2020 16:23:43
User entered 'None (0)'	System	11 Aug 2020 16:23:43

FDA-CBER-2022-1614-0808759

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:50:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:23:21', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '942c3133-8a06-4129-a41d-215cd0fd9c3e'	System	11 Aug 2020 16:23:43
User entered 'None (0)'	System	11 Aug 2020 16:23:43

FDA-CBER-2022-1614-0808760

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:50:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:23:22', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '942c3133-8a06-4129-a41d-215cd0fd9c3e'	System	11 Aug 2020 16:23:43
User entered 'None (0)'	System	11 Aug 2020 16:23:43

FDA-CBER-2022-1614-0808761

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:50:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:23:24', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '942c3133-8a06-4129-a41d-215cd0fd9c3e'	System	11 Aug 2020 16:23:43
User entered 'None (0)'	System	11 Aug 2020 16:23:43

FDA-CBER-2022-1614-0808762

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:50:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:23:25', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '942c3133-8a06-4129-a41d-215cd0fd9c3e'	System	11 Aug 2020 16:23:43
User entered 'None (0)'	System	11 Aug 2020 16:23:43

FDA-CBER-2022-1614-0808763

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:50:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:23:34', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '942c3133-8a06-4129-a41d-215cd0fd9c3e'	System	11 Aug 2020 16:23:43
User entered 'None (0)'	System	11 Aug 2020 16:23:43

FDA-CBER-2022-1614-0808764

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:50:46
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:23:36', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '942c3133-8a06-4129-a41d-215cd0fd9c3e'	System	11 Aug 2020 16:23:43
User entered 'No (N)'	System	11 Aug 2020 16:23:43

FDA-CBER-2022-1614-0808765

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:50:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:23:38', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '942c3133-8a06-4129-a41d-215cd0fd9c3e'	System	11 Aug 2020 16:23:43
User entered '11 Aug 2020 12:23'	System	11 Aug 2020 16:23:43

FDA-CBER-2022-1614-0808766

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808767

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808768

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 6'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808769

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:50:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:08', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '116ba212-9f8d-488d-89d0-4b983d04c956'	System	12 Aug 2020 17:50:18
User entered 'None (0)'	System	12 Aug 2020 17:50:18

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:50:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:09', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '116ba212-9f8d-488d-89d0-4b983d04c956'	System	12 Aug 2020 17:50:18
User entered 'None (0)'	System	12 Aug 2020 17:50:18

FDA-CBER-2022-1614-0808771

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:50:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:10', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '116ba212-9f8d-488d-89d0-4b983d04c956'	System	12 Aug 2020 17:50:18
User entered 'None (0)'	System	12 Aug 2020 17:50:18

FDA-CBER-2022-1614-0808772

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:50:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:11', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '116ba212-9f8d-488d-89d0-4b983d04c956'	System	12 Aug 2020 17:50:18
User entered 'None (0)'	System	12 Aug 2020 17:50:18

FDA-CBER-2022-1614-0808773

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:50:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:13', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '116ba212-9f8d-488d-89d0-4b983d04c956'	System	12 Aug 2020 17:50:18
User entered 'None (0)'	System	12 Aug 2020 17:50:18

FDA-CBER-2022-1614-0808774

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:50:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:14', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '116ba212-9f8d-488d-89d0-4b983d04c956'	System	12 Aug 2020 17:50:18
User entered 'None (0)'	System	12 Aug 2020 17:50:18

FDA-CBER-2022-1614-0808775

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:50:46
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:15', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '116ba212-9f8d-488d-89d0-4b983d04c956'	System	12 Aug 2020 17:50:18
User entered 'No (N)'	System	12 Aug 2020 17:50:18

FDA-CBER-2022-1614-0808776

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:50:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:17', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '116ba212-9f8d-488d-89d0-4b983d04c956'	System	12 Aug 2020 17:50:18
User entered '12 Aug 2020 13:50'	System	12 Aug 2020 17:50:18

FDA-CBER-2022-1614-0808777

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808778

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808779

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 7'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808780

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:50:46
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:52', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6c30bb3d-8580-4d6e-ad30-daad633d0395'	System	13 Aug 2020 16:19:08
User entered 'None (0)'	System	13 Aug 2020 16:19:08

FDA-CBER-2022-1614-0808781

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:50:46
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:53', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6c30bb3d-8580-4d6e-ad30-daad633d0395'	System	13 Aug 2020 16:19:08
User entered 'None (0)'	System	13 Aug 2020 16:19:08

FDA-CBER-2022-1614-0808782

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:50:46
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:55', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6c30bb3d-8580-4d6e-ad30-daad633d0395'	System	13 Aug 2020 16:19:08
User entered 'None (0)'	System	13 Aug 2020 16:19:08

FDA-CBER-2022-1614-0808783

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:50:46
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:56', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6c30bb3d-8580-4d6e-ad30-daad633d0395'	System	13 Aug 2020 16:19:08
User entered 'None (0)'	System	13 Aug 2020 16:19:08

FDA-CBER-2022-1614-0808784

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:50:46
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:57', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6c30bb3d-8580-4d6e-ad30-daad633d0395'	System	13 Aug 2020 16:19:08
User entered 'None (0)'	System	13 Aug 2020 16:19:08

FDA-CBER-2022-1614-0808785

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:50:46
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:58', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6c30bb3d-8580-4d6e-ad30-daad633d0395'	System	13 Aug 2020 16:19:08
User entered 'None (0)'	System	13 Aug 2020 16:19:08

FDA-CBER-2022-1614-0808786

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:50:46
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:59', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6c30bb3d-8580-4d6e-ad30-daad633d0395'	System	13 Aug 2020 16:19:08
User entered 'No (N)'	System	13 Aug 2020 16:19:08

FDA-CBER-2022-1614-0808787

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:50:46
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:19:02', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6c30bb3d-8580-4d6e-ad30-daad633d0395'	System	13 Aug 2020 16:19:08
User entered '13 Aug 2020 12:19'	System	13 Aug 2020 16:19:08

FDA-CBER-2022-1614-0808788

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:50:46
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808789

US3522042
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:50:46
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808790

US3522042
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User closed query 'Was Contact Attempted? = Yes and ‘Date of Contact or Contact Attempt’ or ‘ Please select one status for the follow-up contact’ is missing. Please review and reconcile.' (Site from System).	System	14 Aug 2020 14:42:44
User opened query 'Was Contact Attempted? = Yes and ‘Date of Contact or Contact Attempt’ or ‘ Please select one status for the follow-up contact’ is missing. Please review and reconcile.' (Site from System).	System	14 Aug 2020 14:40:32
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:40:32

FDA-CBER-2022-1614-0808791

US3522042
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '14 Aug 2020'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:40:32

FDA-CBER-2022-1614-0808792

US3522042
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:42:44
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:40:32

FDA-CBER-2022-1614-0808793

US3522042
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Attempted to call patient, did not answer; voicemail was left' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:42:44
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:40:32

FDA-CBER-2022-1614-0808794

US3522042
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:40:39

FDA-CBER-2022-1614-0808795

US3522042
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	14 Aug 2020 14:40:39

FDA-CBER-2022-1614-0808796

US3522042
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4) (b) (4)	21 Aug 2020 18:58:21

FDA-CBER-2022-1614-0808797

US3522042
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '21 Aug 2020'	Jo-Ann Rammal (b) (4) (b) (4)	21 Aug 2020 18:58:21

FDA-CBER-2022-1614-0808798

US3522042
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4) (b) (4)	21 Aug 2020 19:26:40
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jo-Ann Rammal (b) (4) (b) (4)	21 Aug 2020 18:58:21

US3522042
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Pt is good, no adverse events' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4) (b) (4)	21 Aug 2020 19:26:40
User entered 'Left voice message'	Jo-Ann Rammal (b) (4) (b) (4)	21 Aug 2020 18:58:21

US3522042
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4) (b) (4)	21 Aug 2020 19:26:46

FDA-CBER-2022-1614-0808801

US3522042
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	21 Aug 2020 19:26:46

FDA-CBER-2022-1614-0808802

US3522042
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:49:40

FDA-CBER-2022-1614-0808803

US3522042
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 16:49:44
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:49:40

FDA-CBER-2022-1614-0808804

US3522042
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 16:49:44
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:49:40

FDA-CBER-2022-1614-0808805

US3522042
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 16:49:44
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:49:40

FDA-CBER-2022-1614-0808806

US3522042
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:50:23
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:50:57

FDA-CBER-2022-1614-0808807

US3522042
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	28 Sep 2020 18:50:23
User entered '1'	System	21 Sep 2020 16:50:57

FDA-CBER-2022-1614-0808808

US3522042
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:05

FDA-CBER-2022-1614-0808809

US3522042
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:05

FDA-CBER-2022-1614-0808810

US3522042
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:05

FDA-CBER-2022-1614-0808811

US3522042
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'VISIT2'	System	21 Sep 2020 16:51:05

FDA-CBER-2022-1614-0808812

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:50:46
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
DataPoint set to visible.	System	28 Sep 2020 18:50:23
DataPoint set to invisible.	System	21 Sep 2020 16:50:57

FDA-CBER-2022-1614-0808813

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:50:46
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
DataPoint set to visible.	System	28 Sep 2020 18:50:23
DataPoint set to invisible.	System	21 Sep 2020 16:50:57

FDA-CBER-2022-1614-0808814

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:50:46
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
DataPoint set to visible.	System	28 Sep 2020 18:50:23
DataPoint set to invisible.	System	21 Sep 2020 16:50:57

FDA-CBER-2022-1614-0808815

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:50:46
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
DataPoint set to visible.	System	28 Sep 2020 18:50:23
DataPoint set to invisible.	System	21 Sep 2020 16:50:57

FDA-CBER-2022-1614-0808816

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User accepted default value 'Pre-Dose (PREDOSE)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808817

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808818

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808819

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808820

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808821

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808822

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808823

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808824

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808825

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808826

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808827

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808828

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808829

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808830

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808831

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:50:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808832

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:50:46
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
DataPoint set to visible.	System	28 Sep 2020 18:50:23
DataPoint set to invisible.	System	21 Sep 2020 16:50:57

FDA-CBER-2022-1614-0808833

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:50:46
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
DataPoint set to visible.	System	28 Sep 2020 18:50:23
DataPoint set to invisible.	System	21 Sep 2020 16:50:57

FDA-CBER-2022-1614-0808834

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User accepted default value 'Post-Dose (POSTDOSE)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808835

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808836

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808837

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808838

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808839

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808840

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808841

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808842

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808843

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808844

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808845

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808846

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808847

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808848

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808849

US3522042
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:50:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	21 Sep 2020 16:52:14

FDA-CBER-2022-1614-0808850

US3522042
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:50:46
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:40

FDA-CBER-2022-1614-0808851

US3522042
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:50:46
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:40

FDA-CBER-2022-1614-0808852

US3522042
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:35

FDA-CBER-2022-1614-0808853

US3522042
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Confirmed COVID-19 (COVID)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:35

FDA-CBER-2022-1614-0808854

US3522042
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:50:46

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)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:35

FDA-CBER-2022-1614-0808855

US3522042
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	21 Sep 2020 16:51:35

FDA-CBER-2022-1614-0808856

US3522042
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:35

FDA-CBER-2022-1614-0808857

US3522042
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:35

FDA-CBER-2022-1614-0808858

US3522042
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	21 Sep 2020 16:51:35

FDA-CBER-2022-1614-0808859

US3522042
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:35

FDA-CBER-2022-1614-0808860

US3522042
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	21 Sep 2020 16:51:35

FDA-CBER-2022-1614-0808861

US3522042
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:50:46
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	21 Sep 2020 16:51:35

FDA-CBER-2022-1614-0808862

US3522042
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:50:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:24

FDA-CBER-2022-1614-0808863

US3522042
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:50:46
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:24

FDA-CBER-2022-1614-0808864

US3522042
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:50:46
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:24

FDA-CBER-2022-1614-0808865

US3522042
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:50:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	21 Sep 2020 16:51:24

FDA-CBER-2022-1614-0808866

US3522042
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 11 Aug 2021 22:50:46
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:16

FDA-CBER-2022-1614-0808867

US3522042
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:50:46
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:16

FDA-CBER-2022-1614-0808868

US3522042
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:50:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:16

FDA-CBER-2022-1614-0808869

US3522042
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:50:46
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:16

FDA-CBER-2022-1614-0808870

US3522042
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:50:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	21 Sep 2020 16:51:16

FDA-CBER-2022-1614-0808871

US3522042
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:50:46
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:16

FDA-CBER-2022-1614-0808872

US3522042
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:50:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:16

FDA-CBER-2022-1614-0808873

US3522042
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:50:46
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:16

FDA-CBER-2022-1614-0808874

US3522042
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:50:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	21 Sep 2020 16:51:16

FDA-CBER-2022-1614-0808875

US3522042
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:50:12
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:10

FDA-CBER-2022-1614-0808876

US3522042
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	28 Sep 2020 18:50:12
User entered '1'	System	21 Sep 2020 16:51:10

FDA-CBER-2022-1614-0808877

US3522042
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	21 Sep 2020 17:19:05

FDA-CBER-2022-1614-0808878

US3522042
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '10 Sep 2020'	Tyler Prentiss (b) (4) (b) (4)	21 Sep 2020 17:19:05

FDA-CBER-2022-1614-0808879

US3522042
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Contact Made (CONTACT MADE)'	Tyler Prentiss (b) (4) (b) (4)	21 Sep 2020 17:19:05

FDA-CBER-2022-1614-0808880

US3522042
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Patient was COVID-positive; physician Dr. Ramesh was performing active telemedicine and illness visits in lieu of safety phone calls'	Tyler Prentiss (b) (4) (b) (4)	21 Sep 2020 17:19:05

FDA-CBER-2022-1614-0808881

US3522042
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	21 Sep 2020 17:19:09

FDA-CBER-2022-1614-0808882

US3522042
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	21 Sep 2020 17:19:09

FDA-CBER-2022-1614-0808883

US3522042
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	21 Sep 2020 17:19:35

FDA-CBER-2022-1614-0808884

US3522042
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '17 Sep 2020'	Tyler Prentiss (b) (4) (b) (4)	21 Sep 2020 17:19:35

FDA-CBER-2022-1614-0808885

US3522042
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Contact Made (CONTACT MADE)'	Tyler Prentiss (b) (4) (b) (4)	21 Sep 2020 17:19:35

US3522042
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Patient was COVID-positive; physician Dr. Ramesh was performing active telemedicine and illness visits in lieu of safety phone calls'	Tyler Prentiss (b) (4) (b) (4)	21 Sep 2020 17:19:35

FDA-CBER-2022-1614-0808887

US3522042
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	21 Sep 2020 17:19:39

FDA-CBER-2022-1614-0808888

US3522042
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	21 Sep 2020 17:19:39

FDA-CBER-2022-1614-0808889

US3522042
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	24 Sep 2020 16:56:45

FDA-CBER-2022-1614-0808890

US3522042
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '29 Sep 2020' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	29 Sep 2020 18:19:43
User entered '24 Sep 2020'	Kristin Eis (b) (4) (b) (4)	24 Sep 2020 16:56:45

US3522042
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	29 Sep 2020 18:19:43
User entered 'Contact Not Made (CONTACT NOT MADE)'	Kristin Eis (b) (4) (b) (4)	24 Sep 2020 16:56:45

US3522042
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'patient was covid positive, did not receive second dosage has been doing illness visits with study doctor.' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	29 Sep 2020 18:19:43
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	24 Sep 2020 16:58:22
User entered 'patient did not answer; voicemail was left' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	24 Sep 2020 16:58:22
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	24 Sep 2020 16:56:45
User entered empty.	Kristin Eis (b) (4) (b) (4)	24 Sep 2020 16:56:45

FDA-CBER-2022-1614-0808893

US3522042
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	24 Sep 2020 16:57:45

FDA-CBER-2022-1614-0808894

US3522042
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	24 Sep 2020 16:57:45

FDA-CBER-2022-1614-0808895

US3522042
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:54:24

FDA-CBER-2022-1614-0808896

US3522042
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '2 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:54:24

FDA-CBER-2022-1614-0808897

US3522042
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 17:08:43
User entered 'Home (Home)'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:54:24

FDA-CBER-2022-1614-0808898

US3522042
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'VISIT3'	System	02 Oct 2020 16:54:24

FDA-CBER-2022-1614-0808899

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

FDA-CBER-2022-1614-0808900

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User closed query 'Per CDM: Per CCG, Date of assessment should be recorded in (dd-MMM-yyyy) format. Please review and update it accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:32:20
Query 'Per CDM: Per CCG, Date of assessment should be recorded in (dd-MMM-yyyy) format. Please review and update it accordingly. ' answered with 'Please fix medidata. The auto calendar button was used and formats the date as d MMM yyyy. Don't provide a calendar option if it does not format the way you want.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 15:20:27
User entered '02 Oct 2020' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 15:20:22
User opened query 'Per CDM: Per CCG, Date of assessment should be recorded in (dd-MMM-yyyy) format. Please review and update it accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:44:29
User entered '2 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

FDA-CBER-2022-1614-0808901

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User closed query 'Per CDM: Per CCG, Time of assessment should be recorded in 24 HR format (HH:MM) .Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:32:26
Query 'Per CDM: Per CCG, Time of assessment should be recorded in 24 HR format (HH:MM) .Please review and update accordingly.' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 15:20:31
User entered '09:30' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 15:20:22
User opened query 'Per CDM: Per CCG, Time of assessment should be recorded in 24 HR format (HH:MM) .Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:46:14
User entered '9:30'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

FDA-CBER-2022-1614-0808902

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '02 Oct 2020 09:30'	System	06 Nov 2020 15:20:22
User entered '2 Oct 2020 9:30'	System	02 Oct 2020 16:57:07

FDA-CBER-2022-1614-0808903

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '97.6' F	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

FDA-CBER-2022-1614-0808904

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Oral (Oral)'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

FDA-CBER-2022-1614-0808905

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

FDA-CBER-2022-1614-0808906

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '59'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

FDA-CBER-2022-1614-0808907

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'bpm'	System	02 Oct 2020 16:57:07

FDA-CBER-2022-1614-0808908

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '16'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

FDA-CBER-2022-1614-0808909

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'breaths/min'	System	02 Oct 2020 16:57:07

FDA-CBER-2022-1614-0808910

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '137'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

FDA-CBER-2022-1614-0808911

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'mmHg'	System	02 Oct 2020 16:57:07

FDA-CBER-2022-1614-0808912

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '79'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

FDA-CBER-2022-1614-0808913

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'mmHg'	System	02 Oct 2020 16:57:07

FDA-CBER-2022-1614-0808914

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22

FDA-CBER-2022-1614-0808915

US3522042
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22

FDA-CBER-2022-1614-0808916

US3522042
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:50:46
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:54:36

FDA-CBER-2022-1614-0808917

US3522042
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:50:46
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '2 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:54:36

FDA-CBER-2022-1614-0808918

US3522042
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:50:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:26

FDA-CBER-2022-1614-0808919

US3522042
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:50:46
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '2 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:26

FDA-CBER-2022-1614-0808920

US3522042
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:50:46
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered '09:40'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:26

FDA-CBER-2022-1614-0808921

US3522042
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:50:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '2 Oct 2020 09:40'	System	02 Oct 2020 16:57:26

FDA-CBER-2022-1614-0808922

US3522042
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 16:49:44
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:54:42

FDA-CBER-2022-1614-0808923

US3522042
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	02 Oct 2020 16:54:42

FDA-CBER-2022-1614-0808924

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 64'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808925

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-11T10:07:41', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '7c82ec6c-2acf-4fb9-ac06-7962c86c23ab'	System	11 Oct 2020 14:07:51
User entered 'No (N)'	System	11 Oct 2020 14:07:51

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-11T10:07:45', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '7c82ec6c-2acf-4fb9-ac06-7962c86c23ab'	System	11 Oct 2020 14:07:51
User entered 'No (N)'	System	11 Oct 2020 14:07:51

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-11T10:07:47', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '7c82ec6c-2acf-4fb9-ac06-7962c86c23ab'	System	11 Oct 2020 14:07:51
User entered '11 Oct 2020 10:07:47'	System	11 Oct 2020 14:07:51

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808929

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808930

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 71'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808931

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-14T06:30:52', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'da48d99e-65f9-4224-a60b-e7a232097ce7'	System	14 Oct 2020 10:31:02
User entered 'No (N)'	System	14 Oct 2020 10:31:02

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-14T06:30:54', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'da48d99e-65f9-4224-a60b-e7a232097ce7'	System	14 Oct 2020 10:31:02
User entered 'No (N)'	System	14 Oct 2020 10:31:02

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-14T06:30:58', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'da48d99e-65f9-4224-a60b-e7a232097ce7'	System	14 Oct 2020 10:31:02
User entered '14 Oct 2020 06:30:58'	System	14 Oct 2020 10:31:02

FDA-CBER-2022-1614-0808934

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808935

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808936

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 78'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808937

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-21T05:31:56', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '769200a0-5b98-41a1-8c92-9666d04a5616'	System	21 Oct 2020 09:32:06
User entered 'No (N)'	System	21 Oct 2020 09:32:06

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-21T05:32:00', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '769200a0-5b98-41a1-8c92-9666d04a5616'	System	21 Oct 2020 09:32:06
User entered 'No (N)'	System	21 Oct 2020 09:32:06

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-21T05:32:02', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '769200a0-5b98-41a1-8c92-9666d04a5616'	System	21 Oct 2020 09:32:06
User entered '21 Oct 2020 05:32:02'	System	21 Oct 2020 09:32:06

FDA-CBER-2022-1614-0808940

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808941

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808942

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 92'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808943

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-05T12:02:05', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '3c9e8a34-f0a3-4750-80de-5041fb48d9de'	System	05 Nov 2020 17:04:31
User entered 'No (N)'	System	05 Nov 2020 17:04:31

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-05T12:02:09', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '3c9e8a34-f0a3-4750-80de-5041fb48d9de'	System	05 Nov 2020 17:04:31
User entered 'No (N)'	System	05 Nov 2020 17:04:31

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-05T12:02:11', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '3c9e8a34-f0a3-4750-80de-5041fb48d9de'	System	05 Nov 2020 17:04:31
User entered '05 Nov 2020 12:02:11'	System	05 Nov 2020 17:04:31

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808947

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808948

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 99'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808949

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-11T00:01:39', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '823633a8-ff83-4871-a895-46c7833d4206'	System	11 Nov 2020 05:01:52
User entered 'No (N)'	System	11 Nov 2020 05:01:52

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-11T00:01:43', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '823633a8-ff83-4871-a895-46c7833d4206'	System	11 Nov 2020 05:01:52
User entered 'No (N)'	System	11 Nov 2020 05:01:52

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-11T00:01:45', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '823633a8-ff83-4871-a895-46c7833d4206'	System	11 Nov 2020 05:01:52
User entered '11 Nov 2020 00:01:45'	System	11 Nov 2020 05:01:52

FDA-CBER-2022-1614-0808952

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808953

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808954

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 106'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808955

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-18T07:43:02', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '57ed8f1f-a786-4527-8ab8-57b7a20815f3'	System	18 Nov 2020 12:43:08
User entered 'No (N)'	System	18 Nov 2020 12:43:08

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-18T07:43:04', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '57ed8f1f-a786-4527-8ab8-57b7a20815f3'	System	18 Nov 2020 12:43:08
User entered 'No (N)'	System	18 Nov 2020 12:43:08

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-18T07:43:06', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '57ed8f1f-a786-4527-8ab8-57b7a20815f3'	System	18 Nov 2020 12:43:08
User entered '18 Nov 2020 07:43:06'	System	18 Nov 2020 12:43:08

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808959

US3522042
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [redacted]	25 Feb 2021 14:40:13
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 14:57:26

FDA-CBER-2022-1614-0808960

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:35:25

FDA-CBER-2022-1614-0808961

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-25T09:23:08', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '602a2b17-5193-4375-8d08-20afac3171ef'	System	25 Nov 2020 14:23:15
User entered 'No (N)'	System	25 Nov 2020 14:23:15

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-25T09:23:10', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '602a2b17-5193-4375-8d08-20afac3171ef'	System	25 Nov 2020 14:23:15
User entered 'No (N)'	System	25 Nov 2020 14:23:15

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-25T09:23:13', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '602a2b17-5193-4375-8d08-20afac3171ef'	System	25 Nov 2020 14:23:15
User entered '25 Nov 2020 09:23:13'	System	25 Nov 2020 14:23:15

FDA-CBER-2022-1614-0808964

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 15:35:25

FDA-CBER-2022-1614-0808965

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 15:35:25

FDA-CBER-2022-1614-0808966

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:35:25

FDA-CBER-2022-1614-0808967

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-29T12:47:13', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '4111c748-2cb6-4518-a231-616796c5730e'	System	29 Nov 2020 17:47:31
User entered 'No (N)'	System	29 Nov 2020 17:47:31

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-29T12:47:24', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '4111c748-2cb6-4518-a231-616796c5730e'	System	29 Nov 2020 17:47:31
User entered 'No (N)'	System	29 Nov 2020 17:47:31

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-29T12:47:27', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '4111c748-2cb6-4518-a231-616796c5730e'	System	29 Nov 2020 17:47:31
User entered '29 Nov 2020 12:47:27'	System	29 Nov 2020 17:47:31

FDA-CBER-2022-1614-0808970

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 15:35:25

FDA-CBER-2022-1614-0808971

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 15:35:25

FDA-CBER-2022-1614-0808972

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:35:25

FDA-CBER-2022-1614-0808973

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-12-08T12:08:29', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '945075bb-ea3d-477e-881d-e631057e8151'	System	08 Dec 2020 17:08:38
User entered 'No (N)'	System	08 Dec 2020 17:08:38

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-12-08T12:08:31', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '945075bb-ea3d-477e-881d-e631057e8151'	System	08 Dec 2020 17:08:38
User entered 'No (N)'	System	08 Dec 2020 17:08:38

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-12-08T12:08:33', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '945075bb-ea3d-477e-881d-e631057e8151'	System	08 Dec 2020 17:08:38
User entered '08 Dec 2020 12:08:33'	System	08 Dec 2020 17:08:38

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 15:35:25

FDA-CBER-2022-1614-0808977

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 15:35:25

FDA-CBER-2022-1614-0808978

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:35:25

FDA-CBER-2022-1614-0808979

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-12-13T05:44:25', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'ba72a8bb-4105-4183-a368-244f1590a2cb'	System	13 Dec 2020 10:44:35
User entered 'No (N)'	System	13 Dec 2020 10:44:35

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-12-13T05:44:28', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'ba72a8bb-4105-4183-a368-244f1590a2cb'	System	13 Dec 2020 10:44:35
User entered 'No (N)'	System	13 Dec 2020 10:44:35

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-12-13T05:44:30', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'ba72a8bb-4105-4183-a368-244f1590a2cb'	System	13 Dec 2020 10:44:35
User entered '13 Dec 2020 05:44:30'	System	13 Dec 2020 10:44:35

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 15:35:25

FDA-CBER-2022-1614-0808983

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 15:35:25

FDA-CBER-2022-1614-0808984

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:35:25

FDA-CBER-2022-1614-0808985

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-12-21T12:06:03', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'a585f840-68fe-4b2c-9496-db506c0232f5'	System	21 Dec 2020 17:06:10
User entered 'No (N)'	System	21 Dec 2020 17:06:10

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-12-21T12:06:05', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'a585f840-68fe-4b2c-9496-db506c0232f5'	System	21 Dec 2020 17:06:10
User entered 'No (N)'	System	21 Dec 2020 17:06:10

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-12-21T12:06:07', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'a585f840-68fe-4b2c-9496-db506c0232f5'	System	21 Dec 2020 17:06:10
User entered '21 Dec 2020 12:06:07'	System	21 Dec 2020 17:06:10

FDA-CBER-2022-1614-0808988

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 15:35:25

FDA-CBER-2022-1614-0808989

US3522042
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:50:46
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 15:35:25

FDA-CBER-2022-1614-0808990

US3522042
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	29 Oct 2020 14:12:48

FDA-CBER-2022-1614-0808991

US3522042
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '29 Oct 2020'	Yaman Ahmed (b) (4) (b) (4)	29 Oct 2020 14:12:48

FDA-CBER-2022-1614-0808992

US3522042
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Contact Not Made (CONTACT NOT MADE)'	Yaman Ahmed (b) (4) (b) (4)	29 Oct 2020 14:12:48

FDA-CBER-2022-1614-0808993

US3522042
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'left a voicemail'	Yaman Ahmed (b) (4) (b) (4)	29 Oct 2020 14:12:48

FDA-CBER-2022-1614-0808994

US3522042
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	02 Dec 2020 14:55:45

FDA-CBER-2022-1614-0808995

US3522042
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	02 Dec 2020 14:55:45

FDA-CBER-2022-1614-0808996

US3522042
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	02 Dec 2020 14:59:18

FDA-CBER-2022-1614-0808997

US3522042
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '3 Dec 2020' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	03 Dec 2020 19:53:16
User entered '2 Dec 2020'	Yaman Ahmed (b) (4) (b) (4)	02 Dec 2020 14:59:18

FDA-CBER-2022-1614-0808998

US3522042
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	03 Dec 2020 20:17:36
User entered 'Contact Not Made (CONTACT NOT MADE)'	Yaman Ahmed (b) (4) (b) (4)	02 Dec 2020 14:59:18

FDA-CBER-2022-1614-0808999

US3522042
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:50:46
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	03 Dec 2020 20:17:36
User entered '1st attempt 02 Dec 2020; 2nd attempt on 03 Dec 2020; LEFT A VOICEMAIL' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	03 Dec 2020 19:53:16
User entered 'left a voicemail'	Yaman Ahmed (b) (4) (b) (4)	02 Dec 2020 14:59:18

US3522042
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	16 Mar 2021 17:20:38
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	16 Mar 2021 17:20:38
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	03 Dec 2020 20:17:41

FDA-CBER-2022-1614-0809001

US3522042
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:50:46
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	16 Mar 2021 17:20:38
User entered '1'	System	03 Dec 2020 20:17:41

FDA-CBER-2022-1614-0809002

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:50:46
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:58:48
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:10
User entered '24 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 13:59:57

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:50:46
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:58:48
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:10
User entered '09:00'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 13:59:57

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:50:46
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:58:48
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '24 Aug 2020 09:00'	System	24 Aug 2020 13:59:57

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:50:46
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:58:48
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:10
User entered 'Safety Call (Safety Call)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 13:59:57

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:50:46
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:58:48
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:10
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 13:59:57

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 1 (Day 1)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User closed query 'Per CDM: Please confirm initial start date of symptoms and Contact date are the same (24AUG2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 01:44:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
Query 'Per CDM: Please confirm initial start date of symptoms and Contact date are the same (24AUG2020) or update accordingly' answered with 'Symptoms began August 22' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 18:56:15
User entered '22 Aug 2020' reason for change: Data Entry Error	Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 18:55:50
User opened query 'Per CDM: Please confirm initial start date of symptoms and Contact date are the same (24AUG2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:51:58
User entered '24 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:25:02
User entered '22 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

FDA-CBER-2022-1614-0809009

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:25:02
User entered '1'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

FDA-CBER-2022-1614-0809010

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:25:02
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

FDA-CBER-2022-1614-0809011

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	26 Aug 2020 15:25:02
User entered empty.	System	24 Aug 2020 14:11:58

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	30 Apr 2021 18:22:46
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:10:26
User closed query 'Per source temperature is 100.9F on 22AUG2020' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 18:10:24
Query 'Per source temperature is 100.9F on 22AUG2020' answered with 'updated per source ' (Site from CRA).	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:34:37
Signature has been broken.	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:34:12
User entered '100.9' F reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:34:12
User opened query 'Per source temperature is 100.9F on 22AUG2020' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 15:54:18
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 15:53:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.3' F reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:25:02
User entered '100.9' F reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:12:30
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	30 Apr 2021 18:22:46
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:10:31
User closed query 'Per source chills was mild. Please update. ' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 18:10:28
Query 'Per source chills was mild. Please update. ' answered with 'updated per source ' (Site from CRA).	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:34:39
Signature has been broken.	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:34:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:34:12
User opened query 'Per source chills was mild. Please update. ' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 15:59:43
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 15:58:28
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:25:02
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	30 Apr 2021 18:22:46
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:10:36
User closed query 'cough was mild please update. ' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 18:10:33
Query 'cough was mild please update. ' answered with 'updated per source ' (Site from CRA).	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:34:41
Signature has been broken.	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:34:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:34:12
User opened query 'cough was mild please update. ' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 16:00:16
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 15:59:58
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:25:02
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	30 Apr 2021 18:22:46
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:10:41
User closed query 'per source Fatigue was not listed as a symptom. Please update.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 18:10:38
Query 'per source Fatigue was not listed as a symptom. Please update.' answered with 'updated per source ' (Site from CRA).	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:34:42
Signature has been broken.	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:34:12
User entered 'None (None)' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:34:12
User opened query 'per source Fatigue was not listed as a symptom. Please update.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 16:01:48
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 16:01:21
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:25:02
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	30 Apr 2021 18:22:46
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:10:47
User closed query 'Per source Headache was mild. Please update' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 18:10:43
Query 'Per source Headache was mild. Please update' answered with 'updated per source ' (Site from CRA).	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:34:45
Signature has been broken.	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:34:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:34:12
User opened query 'Per source Headache was mild. Please update' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 16:02:20
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 16:02:08
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:25:02
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:28:12
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:25:02
User entered 'Moderate (Moderate)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:12:30
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

FDA-CBER-2022-1614-0809028

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:12:30
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

FDA-CBER-2022-1614-0809029

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User closed query 'Per CDM: Answered as updated, however note that data for Day 2 (23 AUG 2020) and Day 3 (24AUG2020) was not recorded in symptom log. If Not Done, please check Not Done for the applicable Symptom Day and Date.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 05:18:31
Query 'Per CDM: Answered as updated, however note that data for Day 2 (23 AUG 2020) and Day 3 (24AUG2020) was not recorded in symptom log. If Not Done, please check Not Done for the applicable Symptom Day and Date.' answered with 'Please check the end of the list or clarify as lines 22 and 23 have been added as days 2 and 3 before last response of updated. Per Moderna, lines do not have to be in order.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	18 Mar 2021 11:13:53
User closed query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 25Aug2020. Please review data and consider updating to 'Day 4' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 06:26:10
User opened query 'Per CDM: Answered as updated, however note that data for Day 2 (23 AUG 2020) and Day 3 (24AUG2020) was not recorded in symptom log. If Not Done, please check Not Done for the applicable Symptom Day and Date.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 06:25:41
User closed query 'Per CDM: Per sponsor review, please verify data and add entry for Symptom Day 2 (23Aug2020) and Day 3 (24Aug2021) to Symptom Log. If Not Done, please check Not Done for the applicable Symptom Day and Date. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 06:25:41

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 25Aug2020. Please review data and consider updating to 'Day 4' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:45:01
Query 'Per CDM: Per sponsor review, please verify data and add entry for Symptom Day 2 (23Aug2020) and Day 3 (24Aug2021) to Symptom Log. If Not Done, please check Not Done for the applicable Symptom Day and Date. ' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:56
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:46
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:46
User opened query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 25Aug2020. Please review data and consider updating to 'Day 4' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 22:19:17
Query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 25Aug2020. Please review data and consider updating to 'Day 5' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify ' canceled (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 22:18:56
User opened query 'Per CDM: Per sponsor review, please verify data and add entry for Symptom Day 2 (23Aug2020) and Day 3 (24Aug2021) to Symptom Log. If Not Done, please check Not Done for the applicable Symptom Day and Date. ' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 22:18:51
User opened query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 25Aug2020. Please review data and consider updating to 'Day 5' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify ' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 22:18:07
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25

FDA-CBER-2022-1614-0809031

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

FDA-CBER-2022-1614-0809032

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '25 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:28:02
User entered '23 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:28:02
User entered '1'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:28:02
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	26 Aug 2020 15:28:02
User entered empty.	System	24 Aug 2020 14:15:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.1' F reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:28:02
User entered '99' F	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:28:02
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:28:02
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

FDA-CBER-2022-1614-0809044

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'Moderate (Moderate)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:57
User entered 'Day 5 (Day 5)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:57
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 3 (Day 3)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '26 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	26 Aug 2020 15:30:05

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.9' F	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:43:10
User entered 'Day 6 (Day 6)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:43:10
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 4 (Day 4)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '27 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

FDA-CBER-2022-1614-0809077

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

FDA-CBER-2022-1614-0809078

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

FDA-CBER-2022-1614-0809079

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	28 Aug 2020 15:55:22

FDA-CBER-2022-1614-0809080

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.1' F	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

FDA-CBER-2022-1614-0809092

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

FDA-CBER-2022-1614-0809095

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

FDA-CBER-2022-1614-0809096

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:43:21
User entered 'Day 7 (Day 7)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:43:21
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 5 (Day 5)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '28 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	28 Aug 2020 15:56:17

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.5' F	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

FDA-CBER-2022-1614-0809107

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

FDA-CBER-2022-1614-0809108

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

FDA-CBER-2022-1614-0809109

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:43:39
User entered 'Day 8 (Day 8)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:43:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 6 (Day 6)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '29 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

FDA-CBER-2022-1614-0809121

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

FDA-CBER-2022-1614-0809123

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	31 Aug 2020 17:31:42

FDA-CBER-2022-1614-0809124

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.9' F	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

FDA-CBER-2022-1614-0809126

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

FDA-CBER-2022-1614-0809127

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

FDA-CBER-2022-1614-0809128

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

FDA-CBER-2022-1614-0809129

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

FDA-CBER-2022-1614-0809131

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

FDA-CBER-2022-1614-0809132

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

FDA-CBER-2022-1614-0809133

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

FDA-CBER-2022-1614-0809134

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

FDA-CBER-2022-1614-0809135

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

FDA-CBER-2022-1614-0809138

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

FDA-CBER-2022-1614-0809140

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 7 (Day 7)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '30 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

FDA-CBER-2022-1614-0809143

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

FDA-CBER-2022-1614-0809145

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	31 Aug 2020 17:33:13

FDA-CBER-2022-1614-0809146

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98' F	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

FDA-CBER-2022-1614-0809147

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

FDA-CBER-2022-1614-0809148

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

FDA-CBER-2022-1614-0809149

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

FDA-CBER-2022-1614-0809150

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

FDA-CBER-2022-1614-0809151

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

FDA-CBER-2022-1614-0809153

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

FDA-CBER-2022-1614-0809155

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

FDA-CBER-2022-1614-0809157

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

FDA-CBER-2022-1614-0809158

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

FDA-CBER-2022-1614-0809160

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

FDA-CBER-2022-1614-0809161

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

FDA-CBER-2022-1614-0809162

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 8 (Day 8)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

FDA-CBER-2022-1614-0809164

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '31 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

FDA-CBER-2022-1614-0809167

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	31 Aug 2020 17:34:35

FDA-CBER-2022-1614-0809168

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97' F	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

FDA-CBER-2022-1614-0809169

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

FDA-CBER-2022-1614-0809173

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

FDA-CBER-2022-1614-0809174

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

FDA-CBER-2022-1614-0809175

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

FDA-CBER-2022-1614-0809177

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

FDA-CBER-2022-1614-0809178

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

FDA-CBER-2022-1614-0809179

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 9 (Day 9)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

FDA-CBER-2022-1614-0809186

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '1 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	01 Sep 2020 16:09:46

FDA-CBER-2022-1614-0809190

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98.3' F	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

FDA-CBER-2022-1614-0809191

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

FDA-CBER-2022-1614-0809194

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

FDA-CBER-2022-1614-0809196

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

FDA-CBER-2022-1614-0809197

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 10 (Day 10)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

FDA-CBER-2022-1614-0809208

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '2 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	08 Sep 2020 12:47:46

FDA-CBER-2022-1614-0809212

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.9' F	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

FDA-CBER-2022-1614-0809214

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 11 (Day 11)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '3 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	08 Sep 2020 12:48:15

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98.2' F	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

FDA-CBER-2022-1614-0809240

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

FDA-CBER-2022-1614-0809241

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 12 (Day 12)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

FDA-CBER-2022-1614-0809252

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '4 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

FDA-CBER-2022-1614-0809253

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

FDA-CBER-2022-1614-0809255

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	08 Sep 2020 12:49:22

FDA-CBER-2022-1614-0809256

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.9' F	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

FDA-CBER-2022-1614-0809260

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

FDA-CBER-2022-1614-0809261

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

FDA-CBER-2022-1614-0809263

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 13 (Day 13)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

FDA-CBER-2022-1614-0809274

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '5 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	08 Sep 2020 12:50:31

FDA-CBER-2022-1614-0809278

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98.1' F	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

FDA-CBER-2022-1614-0809280

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 14 (Day 14)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '6 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

FDA-CBER-2022-1614-0809299

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	08 Sep 2020 12:51:10

FDA-CBER-2022-1614-0809300

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.9' F	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 15 (Day 15)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '7 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	08 Sep 2020 12:52:05

FDA-CBER-2022-1614-0809322

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.8' F	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User entered 'Day 18 (Day 18)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 16 (Day 16)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

FDA-CBER-2022-1614-0809340

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '08 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

FDA-CBER-2022-1614-0809343

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	22 Sep 2020 16:35:19

FDA-CBER-2022-1614-0809344

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.8' F	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

FDA-CBER-2022-1614-0809346

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

FDA-CBER-2022-1614-0809348

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

FDA-CBER-2022-1614-0809349

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

FDA-CBER-2022-1614-0809350

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

FDA-CBER-2022-1614-0809351

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User entered 'Day 19 (Day 19)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 17 (Day 17)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '09 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	22 Sep 2020 16:35:50

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.1' F	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User entered 'Day 20 (Day 20)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 18 (Day 18)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '10 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	22 Sep 2020 16:36:26

FDA-CBER-2022-1614-0809388

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.6' F	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User entered 'Day 21 (Day 21)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 19 (Day 19)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

FDA-CBER-2022-1614-0809406

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '11 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

FDA-CBER-2022-1614-0809407

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

FDA-CBER-2022-1614-0809409

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	22 Sep 2020 16:38:43

FDA-CBER-2022-1614-0809410

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.9' F	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

FDA-CBER-2022-1614-0809417

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User entered 'Day 22 (Day 22)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 20 (Day 20)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '12 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.9' F	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User entered 'Day 23 (Day 23)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:44:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Day 21 (Day 21)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User closed query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 21SEP2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 01:45:10
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 21SEP2020. Please reconcile or clarify.' answered with 'Symptoms subsided' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 18:58:14
User opened query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 21SEP2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:52:27
User entered '13 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.3' F	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'Day 2 (Day 2)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:58:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered '23 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:49:51
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered '0'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:49:50
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered missing code ND - Not Done.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	15 Mar 2021 13:41:31

FDA-CBER-2022-1614-0809476

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:55:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered '99' F	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

FDA-CBER-2022-1614-0809477

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:11:09
User closed query 'Source states "On 08/23/2020 he had temp of 99F - took tylenol 650 mg times one dose". Please update response as there is no mention of chills.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 18:11:08
Query 'Source states "On 08/23/2020 he had temp of 99F - took tylenol 650 mg times one dose". Please update response as there is no mention of chills.' answered with 'symptoms unchanged from previous day ' (Site from CRA).	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:38:44
User opened query 'Source states "On 08/23/2020 he had temp of 99F - took tylenol 650 mg times one dose". Please update response as there is no mention of chills.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 15:49:34
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:11:16
User closed query 'Source states "On 08/23/2020 he had temp of 99F - took tylenol 650 mg times one dose". Please update response as there is no mention of cough.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 18:11:14
Query 'Source states "On 08/23/2020 he had temp of 99F - took tylenol 650 mg times one dose". Please update response as there is no mention of cough.' answered with 'symptoms unchanged from previous day ' (Site from CRA).	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:38:49
User opened query 'Source states "On 08/23/2020 he had temp of 99F - took tylenol 650 mg times one dose". Please update response as there is no mention of cough.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 15:49:46
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

FDA-CBER-2022-1614-0809479

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:49:54
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

FDA-CBER-2022-1614-0809480

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:49:56
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

FDA-CBER-2022-1614-0809481

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:49:57
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

FDA-CBER-2022-1614-0809482

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:49:59
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

FDA-CBER-2022-1614-0809483

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:11:19
User closed query 'Source states "On 08/23/2020 he had temp of 99F - took tylenol 650 mg times one dose". Please update response as there is no mention of body aches.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 18:11:18
Query 'Source states "On 08/23/2020 he had temp of 99F - took tylenol 650 mg times one dose". Please update response as there is no mention of body aches.' answered with 'symptoms unchanged from previous day ' (Site from CRA).	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:38:53
User opened query 'Source states "On 08/23/2020 he had temp of 99F - took tylenol 650 mg times one dose". Please update response as there is no mention of body aches.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 15:50:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:11:23
User closed query 'Source states "On 08/23/2020 he had temp of 99F - took tylenol 650 mg times one dose". Please update response as there is no mention of headache.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 18:11:21
Query 'Source states "On 08/23/2020 he had temp of 99F - took tylenol 650 mg times one dose". Please update response as there is no mention of headache.' answered with 'symptoms unchanged from previous day ' (Site from CRA).	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:38:58
User opened query 'Source states "On 08/23/2020 he had temp of 99F - took tylenol 650 mg times one dose". Please update response as there is no mention of headache.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 15:50:42
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

FDA-CBER-2022-1614-0809485

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:50:43
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

FDA-CBER-2022-1614-0809486

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:11:39
User closed query 'Source states "On 08/23/2020 he had temp of 99F - took tylenol 650 mg times one dose". Please update response as there is no mention of loss of smell.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 18:11:36
Query 'Source states "On 08/23/2020 he had temp of 99F - took tylenol 650 mg times one dose". Please update response as there is no mention of loss of smell.' answered with 'symptoms unchanged from previous day ' (Site from CRA).	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:39:02
User opened query 'Source states "On 08/23/2020 he had temp of 99F - took tylenol 650 mg times one dose". Please update response as there is no mention of loss of smell.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 15:50:59
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'Moderate (Moderate)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

FDA-CBER-2022-1614-0809487

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:51:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

FDA-CBER-2022-1614-0809488

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:51:04
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

FDA-CBER-2022-1614-0809489

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:51:07
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

FDA-CBER-2022-1614-0809490

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:51:09
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

FDA-CBER-2022-1614-0809491

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:51:12
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

FDA-CBER-2022-1614-0809492

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:51:14
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:41:31

FDA-CBER-2022-1614-0809493

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'Day 3 (Day 3)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:58:50
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered '24 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

FDA-CBER-2022-1614-0809495

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:47:18
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered '0'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

FDA-CBER-2022-1614-0809496

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:47:16
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered missing code ND - Not Done.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '%'	System	15 Mar 2021 13:42:30

FDA-CBER-2022-1614-0809498

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:58:45
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered '98' F	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

FDA-CBER-2022-1614-0809499

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:47:20
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

FDA-CBER-2022-1614-0809500

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:47:22
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

FDA-CBER-2022-1614-0809501

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:47:24
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:47:25
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:47:27
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:47:28
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:45:32
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:47:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

FDA-CBER-2022-1614-0809507

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:47:31
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

FDA-CBER-2022-1614-0809508

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:11:50
User closed query 'Loss of smell wa not listed as one of the ongoing symptoms on 24AUG2020. Please update.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 18:11:48
Query 'Loss of smell wa not listed as one of the ongoing symptoms on 24AUG2020. Please update.' answered with 'symptom unchanged from previous day ' (Site from CRA).	Alandra White (b) (4) (b) (4)	30 Apr 2021 17:39:25
User opened query 'Loss of smell wa not listed as one of the ongoing symptoms on 24AUG2020. Please update.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 15:46:32
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'Moderate (Moderate)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:47:34
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:47:36
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:47:38
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

FDA-CBER-2022-1614-0809512

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:47:39
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:47:41
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

FDA-CBER-2022-1614-0809514

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:50:46
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:47:44
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 17:59:14
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:42:30

FDA-CBER-2022-1614-0809515

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:50:46
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:57
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:49
User entered '24 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 17:26:56
User entered '22 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:09:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:50:46
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:57
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:49
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:09:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:50:46
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:57
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:49
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)	31 Aug 2020 15:26:41
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 'COVID-19 diagnosis entered on the Adverse events form' (Site from System).	mayur ramesh (b) (4) (b) (4)	29 Aug 2020 18:03:25
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	24 Aug 2020 14:09:33
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:09:33

FDA-CBER-2022-1614-0809518

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:50:46
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:57
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:49
User entered '24 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 17:26:56
User entered '22 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:09:33

FDA-CBER-2022-1614-0809519

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:50:46
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:57
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:49
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:09:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:50:46
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:57
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:49
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:09:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:50:46

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)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:57
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:49
User entered 'No (N)' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 17:26:30
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:09:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:50:46
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:57
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:49
User entered empty; reason for change New Information	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 17:26:30
User entered 'Henry Ford Microbiology'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:09:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:50:46
CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:57
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:49
User entered empty; reason for change New Information	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 17:26:30
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:09:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:50:46
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:59:57
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	24 Aug 2020 14:09:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Respiratory Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Did the subject have Heart Rate ≥ 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:36:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 11:36:02
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:36:02
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:35:33
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Heart Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
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)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:36:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 11:36:02
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:36:02
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:35:33
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:36:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 11:36:02
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:36:02
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:35:33
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:36:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 11:36:02
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:36:02
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:35:33
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:36:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 11:36:02
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:36:02
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:35:33
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
High-Flow Oxygen?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Mechanical Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
ECMO?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:02:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User closed query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 05:38:24
Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly.' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	05 Jan 2021 14:36:34
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	05 Jan 2021 14:35:54
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	05 Jan 2021 14:35:54
User opened query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 22:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Evidence of Shock Requires Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Acute Renal Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Hepatic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Neurologic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Clinical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:03:00
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	05 Jan 2021 14:35:54
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	05 Jan 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Radiographical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Admission to an intensive care unit due to SARS-CoV-2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User closed query 'Per CDM: it appears ICU is recorded as NO but a date is present. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 05:29:56
Query 'Per CDM: it appears ICU is recorded as NO but a date is present. Please reconcile and update accordingly.' answered with 'Misunderstanding. Thought it was start and end of COV2 infection. Removed' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:28:09
User opened query 'Per CDM: it appears ICU is recorded as NO but a date is present. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:21:43
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:36:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 11:36:02
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:36:02
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:35:33
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:27:38
User entered '22 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:36:02
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:50:46
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042
Folder: Covid-19 Assessment 24 Aug 2020
Form: Generate Next COVID-19 Assessment
Generated On: 11 Aug 2021 22:50:46
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:52
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:00:10
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	09 Mar 2021 15:34:36
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	08 Mar 2021 21:09:23

FDA-CBER-2022-1614-0809577

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:50:46
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User accepted default value 'Day 3 (Day 3)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

FDA-CBER-2022-1614-0809578

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:50:46
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:23
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

FDA-CBER-2022-1614-0809579

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:50:46
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:23
User entered '26 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

FDA-CBER-2022-1614-0809580

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:50:46
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User accepted default value 'Day 5 (Day 5)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

FDA-CBER-2022-1614-0809581

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:50:46
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:25
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 18:04:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 18:04:37
User entered 'Yes (Y)' reason for change: Data Entry Error	mayur ramesh (b) (4) (b) (4)	29 Aug 2020 18:04:37
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 15:34:21
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

FDA-CBER-2022-1614-0809582

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:50:46
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:25
User entered '28 Aug 2020' reason for change: Data Entry Error	mayur ramesh (b) (4) (b) (4)	29 Aug 2020 18:04:37
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:50:46
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User accepted default value 'Day 7 (Day 7)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

FDA-CBER-2022-1614-0809584

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:50:46
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:28
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 17:35:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 17:35:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:35:08
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 15:34:21
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

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US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:50:46
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:28
User entered '30 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:35:08
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:50:46
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User accepted default value 'Day 9 (Day 9)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

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US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:50:46
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:09
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 16:14:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 16:14:35
User entered 'Yes (Y)' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:14:35
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 15:34:21
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:50:46
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:09
User entered '1 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:14:35
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

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US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:50:46
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User accepted default value 'Day 14 (Day 14)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

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US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:50:46
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:29
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 10:16:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 10:16:03
User entered 'Yes (Y)' reason for change: Data Entry Error	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 10:16:03
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 15:34:21
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:50:46
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:29
User entered '06 Sep 2020' reason for change: Data Entry Error	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 10:16:03
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:50:46
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User accepted default value 'Day 21 (Day 21)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

FDA-CBER-2022-1614-0809593

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:50:46
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:41:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 02:14:20
Query 'Data is required. Please complete.' answered with 'waiting to enter until day 21' (Site from System).	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 18:54:23
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 15:34:21
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

FDA-CBER-2022-1614-0809594

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:50:46
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:08
User entered '13 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:41:01
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:50:46
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User accepted default value 'Day 28 (Day 28)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

FDA-CBER-2022-1614-0809596

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:50:46
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:41:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 02:15:38
Query 'Data is required. Please complete.' answered with 'waiting to enter until day 28' (Site from System).	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 18:54:46
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 15:34:21
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

FDA-CBER-2022-1614-0809597

US3522042
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:50:46
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:46
User entered '21 Sep 2020' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:41:40
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

US3522042
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:17
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:31:21

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US3522042
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:17
User entered '24 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:31:21

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US3522042
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:17
User entered 'Clinic (Clinic)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:31:21

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US3522042
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'SICKD1'	System	26 Aug 2020 15:31:21

FDA-CBER-2022-1614-0809602

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

FDA-CBER-2022-1614-0809603

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered '24 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

FDA-CBER-2022-1614-0809604

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:52:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User closed query 'Unable to locate time per source review. Please review and advise to time location in source.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 12:06:01
Query 'Unable to locate time per source review. Please review and advise to time location in source.' answered with 'Made it more clear in Source' (Site from CRA).	Sharon Mathys (b) (4) (b) (4)	17 Sep 2020 15:31:19
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:28
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User opened query 'Unable to locate time per source review. Please review and advise to time location in source.' (Site from CRA).	(b) (4), (b) (6)	10 Sep 2020 20:07:53
User entered '16:05'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '24 Aug 2020 16:05'	System	26 Aug 2020 15:33:18

FDA-CBER-2022-1614-0809606

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 15:33:52
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 15:33:52
User entered '67' in reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:52
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 15:33:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18
DataPoint set to visible.	System	26 Aug 2020 15:31:21

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 15:33:52
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 15:33:52
User entered '178.2' lb reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:52
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 15:33:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18
DataPoint set to visible.	System	26 Aug 2020 15:31:21

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered '97.3' F	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

FDA-CBER-2022-1614-0809609

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered 'Oral (Oral)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

FDA-CBER-2022-1614-0809610

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

FDA-CBER-2022-1614-0809611

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered '60'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

FDA-CBER-2022-1614-0809612

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'bpm'	System	26 Aug 2020 15:33:18

FDA-CBER-2022-1614-0809613

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered '14'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

FDA-CBER-2022-1614-0809614

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'breaths/min'	System	26 Aug 2020 15:33:18

FDA-CBER-2022-1614-0809615

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered '129'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

FDA-CBER-2022-1614-0809616

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'mmHg'	System	26 Aug 2020 15:33:18

FDA-CBER-2022-1614-0809617

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered '93'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

FDA-CBER-2022-1614-0809618

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'mmHg'	System	26 Aug 2020 15:33:18

FDA-CBER-2022-1614-0809619

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22

FDA-CBER-2022-1614-0809620

US3522042
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22

FDA-CBER-2022-1614-0809621

US3522042
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:50:46
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:36
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:31:29

FDA-CBER-2022-1614-0809622

US3522042
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:50:46
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:36
User entered '24 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:31:29

FDA-CBER-2022-1614-0809623

US3522042
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:50:46
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:40
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:05

US3522042
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:50:46
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:40
User entered '24 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:05

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:26
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:41:53

FDA-CBER-2022-1614-0809626

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:26
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:41:53

FDA-CBER-2022-1614-0809627

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:26
User entered 'Clinic (Clinic)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:41:53

FDA-CBER-2022-1614-0809628

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'SICKD28'	System	22 Sep 2020 16:41:53

FDA-CBER-2022-1614-0809629

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:06
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

FDA-CBER-2022-1614-0809630

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:06
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

FDA-CBER-2022-1614-0809631

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:06
User entered '11:32'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '21 Sep 2020 11:32'	System	22 Sep 2020 16:48:40

FDA-CBER-2022-1614-0809633

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:06
User closed query 'Per CDM: Per CCG, data to be entered for “height and weight”. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:42:49
Query 'Per CDM: Per CCG, data to be entered for “height and weight”. Please update accordingly. ' answered with 'was not measured at visit' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 15:09:12
User opened query 'Per CDM: Per CCG, data to be entered for “height and weight”. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:15:19
User entered missing code ND - Not Done.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40
DataPoint set to visible.	System	22 Sep 2020 16:41:53

FDA-CBER-2022-1614-0809634

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:06
User closed query 'Per CDM: Per CCG, data to be entered for “height and weight”. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:42:52
Query 'Per CDM: Per CCG, data to be entered for “height and weight”. Please update accordingly. ' answered with 'was not measured at visit' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 15:09:18
User opened query 'Per CDM: Per CCG, data to be entered for “height and weight”. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:15:26
User entered missing code ND - Not Done.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40
DataPoint set to visible.	System	22 Sep 2020 16:41:53

FDA-CBER-2022-1614-0809635

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:21
User entered '97.8' F	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

FDA-CBER-2022-1614-0809636

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:50
User entered 'Oral (Oral)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

FDA-CBER-2022-1614-0809637

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:51
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

FDA-CBER-2022-1614-0809638

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:54
User entered '55'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

FDA-CBER-2022-1614-0809639

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'bpm'	System	22 Sep 2020 16:48:40

FDA-CBER-2022-1614-0809640

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:59
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:27:54
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	22 Sep 2020 18:27:54
User entered '16' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:27:54
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 16:48:40
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'breaths/min'	System	22 Sep 2020 18:27:54
User entered empty.	System	22 Sep 2020 16:48:40

FDA-CBER-2022-1614-0809642

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:01
User entered '139'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

FDA-CBER-2022-1614-0809643

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'mmHg'	System	22 Sep 2020 16:48:40

FDA-CBER-2022-1614-0809644

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:03
User entered '93'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

FDA-CBER-2022-1614-0809645

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'mmHg'	System	22 Sep 2020 16:48:40

FDA-CBER-2022-1614-0809646

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22

FDA-CBER-2022-1614-0809647

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:50:46
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22

FDA-CBER-2022-1614-0809648

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:50:46
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:10
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:42:03

FDA-CBER-2022-1614-0809649

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:50:46
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:10
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:42:03

FDA-CBER-2022-1614-0809650

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:50:46
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:26
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:51:53

US3522042
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:50:46
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:26
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:51:53

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	19 Feb 2021 16:46:36

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Feb 2021 16:46:36

FDA-CBER-2022-1614-0809654

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Feb 2021 16:46:36

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:50:46
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered 'UNBLND_DECIDE'	System	19 Feb 2021 16:46:36

FDA-CBER-2022-1614-0809656

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:50:46
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	03 Mar 2021 07:12:04
Query 'Data is required. Please complete.' answered with 'visit was not performed. no updated consent signed. done under amendment 5' (Site from System).	Sharon Mathys (b) (4) (b) (4)	01 Mar 2021 18:10:57
Amendment Manager: User opened query 'Data is required. Please complete.' (Site from System).	System	27 Feb 2021 11:36:49
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Feb 2021 16:46:30

FDA-CBER-2022-1614-0809657

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:50:46
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:13:37
User entered '1' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:34:01

FDA-CBER-2022-1614-0809658

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:50:46
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	19 Feb 2021 16:46:30

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:50:46
Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:13:37
User entered 'AMENDMENT 5 (AMENDMENT 5)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:34:01

FDA-CBER-2022-1614-0809660

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:50:46
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '24 Dec 2020'	Sharon Mathys (b) (4) (b) (4)	19 Feb 2021 16:46:30

FDA-CBER-2022-1614-0809661

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:50:46
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Placebo (Placebo)'	Sharon Mathys (b) (4) (b) (4)	19 Feb 2021 16:46:30

FDA-CBER-2022-1614-0809662

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:50:46
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Placebo (Placebo)'	Sharon Mathys (b) (4) (b) (4)	19 Feb 2021 16:46:30

FDA-CBER-2022-1614-0809663

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:50:46
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'Placebo (Placebo)'	Sharon Mathys (b) (4) (b) (4)	19 Feb 2021 16:46:30

FDA-CBER-2022-1614-0809664

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:50:46
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	19 Feb 2021 16:46:30

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:50:46
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	19 Feb 2021 16:46:30

FDA-CBER-2022-1614-0809666

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:50:46
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	19 Feb 2021 16:46:30

FDA-CBER-2022-1614-0809667

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:50:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	19 Feb 2021 16:46:45

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:50:46
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Feb 2021 16:46:45

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:50:46
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Feb 2021 16:46:45

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:50:46
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	19 Feb 2021 16:46:45

FDA-CBER-2022-1614-0809671

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 22:50:46
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	19 Feb 2021 16:46:54

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 22:50:46
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Feb 2021 16:46:54

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 22:50:46
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Feb 2021 16:46:54

FDA-CBER-2022-1614-0809674

US3522042
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 22:50:46
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	19 Feb 2021 16:46:54

FDA-CBER-2022-1614-0809675

US3522042
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 11 Aug 2021 22:50:46
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:54
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 13:51:07

FDA-CBER-2022-1614-0809676

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:20:59
User entered 'USA-US131-2020-mRNA-1273-P301000001'	System	24 Aug 2020 16:20:43
User entered 'New'	(b) (4), (b) (6)	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809677

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:26
Data point term sent to Coder	System	23 Nov 2020 20:59:20
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' canceled (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:59:01
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 12:23:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Per DM CLR: Please review and confirm if AE#2-7 were symptoms of this AE (COVID-19 INFECTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis, and remove duplicate data as appropriate. Update eCRF as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 07:59:04
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 11:59:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 11:59:52

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US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Adverse event

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review and confirm if AE#2-7 were symptoms of this AE (COVID-19 INFECTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis, and remove duplicate data as appropriate. Update eCRF as appropriate. Otherwise, clarify.' answered with 'updated name to say symptomatic covid-19 per ecrf guideline. deactivating all other symptom lines' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 11:59:19
Data point term sent to Coder	System	30 Oct 2020 11:58:52
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 11:58:36
User entered 'Symptomatic COVID-19' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 11:58:36
User opened query 'Per DM CLR: Please review and confirm if AE#2-7 were symptoms of this AE (COVID-19 INFECTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis, and remove duplicate data as appropriate. Update eCRF as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:51:58
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:26:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:26:41
Data point term sent to Coder	System	24 Aug 2020 14:25:53
User entered 'COVID-19 Infection'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

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US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:30:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 14:30:43
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:30:43
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:25:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Per ETRTR: Please complete data entry in Illness Visit as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:37:34
Query 'Per ETRTR: Please complete data entry in Illness Visit as required, thanks.' answered with 'have been doing. entered in source, transferred initial on 8/26' (Site from CRA).	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:26:44
User opened query 'Per ETRTR: Please complete data entry in Illness Visit as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 15:50:20
User entered '22 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Aug 2020 14:30:57
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:30:57
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Aug 2020 14:25:38
User entered '09:00'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

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US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	24 Aug 2020 14:30:57
User entered '22 Aug 2020 09:00'	System	24 Aug 2020 14:25:38

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US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:33:01
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '30 Aug 2020' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	19 Sep 2020 21:27:09
User closed query 'PV Query: Please provide the event end date (resolution of symptoms), when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 22:11:25
Query 'PV Query: Please provide the event end date (resolution of symptoms), when available. Please leave query open until information is available.' answered with 'Symptom free earlier but negative salive test on day 7' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:33:22
User entered '31 Aug 2020' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:33:01
User opened query 'PV Query: Please provide the event end date (resolution of symptoms), when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 13:53:05
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

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US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Per ETRTR: Please provide the event end date, when available.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:37:41
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	31 Aug 2020 12:49:26
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'ongoing but improving ' (Site from Safety).	mayur ramesh (b) (4) (b) (4)	29 Aug 2020 17:51:09
Query 'Per ETRTR: Please provide the event end date, when available.' answered with 'ongoing' (Site from CRA).	mayur ramesh (b) (4) (b) (4)	29 Aug 2020 17:50:32
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 18:10:09
User opened query 'Per ETRTR: Please provide the event end date, when available.' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 15:41:32
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

FDA-CBER-2022-1614-0809688

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered empty.	System	24 Aug 2020 14:25:38

FDA-CBER-2022-1614-0809689

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Per CDM: please confirm if this event meets SAE criteria and update accordingly' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 05:17:06
Query 'Per CDM: please confirm if this event meets SAE criteria and update accordingly' answered with 'does not meet serious criteria' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	16 Oct 2020 15:02:59
User opened query 'Per CDM: please confirm if this event meets SAE criteria and update accordingly' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 00:11:34
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

FDA-CBER-2022-1614-0809692

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

FDA-CBER-2022-1614-0809694

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

FDA-CBER-2022-1614-0809695

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

FDA-CBER-2022-1614-0809696

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

FDA-CBER-2022-1614-0809697

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

FDA-CBER-2022-1614-0809698

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

FDA-CBER-2022-1614-0809700

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

FDA-CBER-2022-1614-0809701

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:59:08
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	14 Sep 2020 18:33:01
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	14 Sep 2020 13:54:26
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	14 Sep 2020 13:52:42
User closed query 'PV Query: Relationship to investigational product and study procedure has been reported as Not applicable. Per protocol, appropriate response would be either Related or Not related. Please updated causality assessment accordingly. ' (Site from Safety).	(b) (4), (b) (6)	31 Aug 2020 12:49:32
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	29 Aug 2020 17:54:10
Query 'PV Query: Relationship to investigational product and study procedure has been reported as Not applicable. Per protocol, appropriate response would be either Related or Not related. Please updated causality assessment accordingly. ' answered with 'ok' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:52:18
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	28 Aug 2020 13:50:52

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Relationship to investigational product

Audit	User	Time (GMT)
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	28 Aug 2020 13:50:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:50:52
User opened query 'PV Query: Relationship to investigational product and study procedure has been reported as Not applicable. Per protocol, appropriate response would be either Related or Not related. Please updated causality assessment accordingly. ' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 18:09:45
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	27 Aug 2020 11:34:29
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	24 Aug 2020 14:31:25
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:31:25
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:30:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 14:30:43
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	24 Aug 2020 14:30:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:30:43
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:25:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:51:13
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:31:25
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:30:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 14:30:43
User entered 'Related (RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:30:43
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:25:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

FDA-CBER-2022-1614-0809704

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	16 Oct 2020 15:04:31
User entered 'None (NONE)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 19:59:08
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 05:14:17
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please consider updating action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 22:11:35
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please consider updating action taken to withdrawn.' answered with 'Updated action to withdrawn' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:35:43
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'COV2 positive diagnosis is not related to IP or to study procedure but is a reason to withdraw IP' (Site from System).	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:35:32
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 18:33:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 18:33:01

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	14 Sep 2020 18:33:01
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:33:01
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 13:54:26
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	14 Sep 2020 13:54:26
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	14 Sep 2020 13:54:26
User entered empty; reason for change Data Entry Error	Jelena Verkler (b) (4) (b) (4)	14 Sep 2020 13:54:26
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	14 Sep 2020 13:52:42
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Jelena Verkler (b) (4) (b) (4)	14 Sep 2020 13:52:42
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please consider updating action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 13:53:52
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	mayur ramesh (b) (4) (b) (4)	29 Aug 2020 17:54:10
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:34:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 11:34:29

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:34:29
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:31:25
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:31:25
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:30:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 14:30:43
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:30:43
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:25:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #3 recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 11:46:42
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #3 recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	09 Nov 2020 14:48:34
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	09 Nov 2020 14:48:29
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #3 recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:32:12
User entered '1'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

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US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	09 Nov 2020 14:48:29
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

FDA-CBER-2022-1614-0809709

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

FDA-CBER-2022-1614-0809710

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
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)	15 Sep 2020 22:11:43
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 'Recovered from infection. Still finishing illness to go to convalescence visit.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:36:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:33:01
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 13:53:25
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)	31 Aug 2020 12:49:45
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 'expected to resolve' (Site from Safety).	mayur ramesh (b) (4) (b) (4)	29 Aug 2020 17:52:48
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)	27 Aug 2020 18:10:49

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US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Outcome

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

FDA-CBER-2022-1614-0809712

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Per DM CLR: SAE Narrative = TOOK TYLENOL 650 MG ONCE, 24 TEMP 98, MILD BODY ACHES, TYLENOL 650 MG ONCE IN MORNING. However, CM indication is FEVER at CM eCRF. Please review and verify if the same medication was given for this AE. If yes, add this AE to the CM indication so there will be an appropriate match. Update eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 07:59:16
Query 'Per DM CLR: SAE Narrative = TOOK TYLENOL 650 MG ONCE, 24 TEMP 98, MILD BODY ACHES, TYLENOL 650 MG ONCE IN MORNING. However, CM indication is FEVER at CM eCRF. Please review and verify if the same medication was given for this AE. If yes, add this AE to the CM indication so there will be an appropriate match. Update eCRF as appropriate. Otherwise, clarify. ' answered with 'updated concom med to state it was for symptomatic covid-19 as it was for a fever on one day and body aches the next, but both were due to covid-19' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 11:58:22
User opened query 'Per DM CLR: SAE Narrative = TOOK TYLENOL 650 MG ONCE, 24 TEMP 98, MILD BODY ACHES, TYLENOL 650 MG ONCE IN MORNING. However, CM indication is FEVER at CM eCRF. Please review and verify if the same medication was given for this AE. If yes, add this AE to the CM indication so there will be an appropriate match. Update eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:51:10

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US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Narrative

Audit	User	Time (GMT)
User entered 'Participant CONTACTED US ON 8/24/2020 TO TELL US HE HAD SYMPTOMS AND TESTED POSITIVE FOR COVID-19 ON 8/22/2020 AFTER PREVIOUSLY ATTENDING A FAMILY GATHERING WHICH LATER HAD MULTIPLE MEMBERS TEST POSITIVE. INITIAL SYMPOTOMS ON THE 22ND WAS 100.9 F, MILD CHILLS, MILD HEADACHE, MODERATE LOSS OF SMELL, MILD COUGH, MILD BODY ACHES. NO MEDS TAKEN. 23RD TEMP WAS 99, TOOK TYLENOL 650 MG ONCE, 24 TEMP 98, MILD BODY ACHES, TYLENOL 650 MG ONCE IN MORNING. IN AFTERNOON WENT TO ILLNESS VISIT AT CLINIC SO DAY 1 FOR STUDY OBSERVATION IS DAY 3 OF INFECTION. ILLNESS VISIT D1 SWAB SENT TO VIRACOR AND TESTED POSITIVE. DAY 7 SALIVA FROM 30 AUG 2020 TESTED NEGATIVE' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	16 Oct 2020 15:06:14
User entered 'PARTIcICPANT CONTACTED US ON 8/24/2020 TO TELL US HE HAD SYMPTOMS AND TESTED POSITIVE FOR COVID-19 ON 8/22/2020 AFTER PREVIOUSLY ATTENDING A FAMILY GATHERING WHICH LATER HAD MULTIPLE MEMBERS TEST POSITIVE. INITIAL SYMPOTOMS ON THE 22ND WAS 100.9 F, MILD CHILLS, MILD HEADACHE, MODERATE LOSS OF SMELL, MILD COUGH, MILD BODY ACHES. NO MEDS TAKEN. 23RD TEMP WAS 99, TOOK TYLENOL 650 MG ONCE, 24 TEMP 98, MILD BODY ACHES, TYLENOL 650 MG ONCE IN MORNING. IN AFTERNOON WENT TO ILLNESS VISIT AT CLINIC SO DAY 1 FOR STUDY OBSERVATION IS DAY 3 OF INFECTION. ILLNESS VISIT D1 SWAB SENT TO VIRACOR AND TESTED POSITIVE. DAY 7 SALIVA FROM 30 AUG 2020 TESTED NEGATIVE' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	16 Oct 2020 15:05:02
User closed query 'PV Query: Please provide the date of negative saliva test.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:12:57

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide the date of negative saliva test.' answered with '30 AUG 2020 test was negative' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	19 Sep 2020 21:26:36
User entered 'PARTIFICPANT CONTACTED US ON 8/24/2020 TO TELL US HE HAD SYMPTOMS AND TESTED POSITIVE FOR COVID-19 ON 8/22/2020 AFTER PREVIOUSLY ATTENDING A FAMILY GATHERING WHICH LATER HAD MULTIPLE MEMBERS TEST POSITIVE. INITIAL SYMPOTOMS ON THE 22ND WAS 100.9 F, MILD CHILLS, MILD HEADACHE, MODERATE LOSS OF SMELL, MILD COUGH, MILD BODY ACHES. NO MEDS TAKEN. 23RD TEMP WAS 99, TOOK TYLENOL 650 MG ONCE, 24 TEMP 98, MILD BODY ACHES, TYLENOL 650 MG ONCE IN MORNING. IN AFTERNOON WENT TO ILLNESS VISIT AT CLINIC SO DAY 1 FOR STUDY OBSERVATION IS DAY 3 OF INFECTION. ILLNESS VISIT D1 SWAB SENT TO VIRACOR AND TESTED POSITIVE. Day 7 saliva from 30 Aug 2020 tested negative' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	19 Sep 2020 21:26:24
User opened query 'PV Query: Please provide the date of negative saliva test.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 15:01:13
User closed query 'PV Query: Please confirm if the patient had any known exposure to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 22:11:52
User closed query 'PV Query: Thank you for confirming that seasonal allergies is considered medical history. Please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 22:11:47
Query 'PV Query: Please confirm if the patient had any known exposure to COVID-19.' answered with 'Added to the narrative about the family gathering.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:41:48

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Narrative

Audit	User	Time (GMT)
User entered 'PARTIFICPANT CONTACTED US ON 8/24/2020 TO TELL US HE HAD SYMPTOMS AND TESTED POSITIVE FOR COVID-19 ON 8/22/2020 after previously attending a family gathering which later had multiple members test positive. INITIAL SYMPOTOMS ON THE 22ND WAS 100.9 F, MILD CHILLS, MILD HEADACHE, MODERATE LOSS OF SMELL, MILD COUGH, MILD BODY ACHES. NO MEDS TAKEN. 23RD TEMP WAS 99, TOOK TYLENOL 650 MG ONCE, 24 TEMP 98, MILD BODY ACHES, TYLENOL 650 MG ONCE IN MORNING. IN AFTERNOON WENT TO ILLNESS VISIT AT CLINIC SO DAY 1 FOR STUDY OBSERVATION IS DAY 3 OF INFECTION. ILLNESS VISIT D1 SWAB SENT TO VIRACOR AND TESTED POSITIVE.' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:41:35
Query 'PV Query: Thank you for confirming that seasonal allergies is considered medical history. Please add to MH eCRF.' answered with 'Added' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:40:08
User closed query 'Per ETRTR: COVID + Narrative should describe clinical course of events, dates, times, treatments (include in ConMeds CRF) and any other assessments which help explain the event. Please add as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:37:48
User opened query 'PV Query: Please confirm if the patient had any known exposure to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 13:54:04
User opened query 'PV Query: Thank you for confirming that seasonal allergies is considered medical history. Please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 13:53:36
User closed query 'PV Query: Please provide results of additional SARS-CoV-2 PCR tests (if and when performed), including Day 1 results.' (Site from Safety).	(b) (4), (b) (6)	31 Aug 2020 12:50:06

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Narrative

Audit	User	Time (GMT)
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)	31 Aug 2020 12:50:02
User closed query 'PV Query: Please confirm if hypertension and seasonal allergies were part of subject's medical history or were considered as AEs. Please report them accordingly in EDC.' (Site from Safety).	(b) (4), (b) (6)	31 Aug 2020 12:49:55
User closed query 'PV Query: Please add subject's medical history (prior to Day 1) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	31 Aug 2020 12:49:51
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 'no treatment ' (Site from Safety).	mayur ramesh (b) (4) (b) (4)	29 Aug 2020 17:54:03
Query 'PV Query: Please confirm if hypertension and seasonal allergies were part of subject's medical history or were considered as AEs. Please report them accordingly in EDC.' answered with 'medical history' (Site from Safety).	mayur ramesh (b) (4) (b) (4)	29 Aug 2020 17:53:33
Query 'Per ETRTR: COVID + Narrative should describe clinical course of events, dates, times, treatments (include in ConMeds CRF) and any other assessments which help explain the event. Please add as required, thanks.' answered with 'completed' (Site from CRA).	mayur ramesh (b) (4) (b) (4)	29 Aug 2020 17:53:08
Query 'PV Query: Please provide results of additional SARS-CoV-2 PCR tests (if and when performed), including Day 1 results.' answered with 'ok' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:58:17

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Narrative

Audit	User	Time (GMT)
User entered 'PARTIFICPANT CONTACTED US ON 8/24/2020 TO TELL US HE HAD SYMPTOMS AND TESTED POSITIVE FOR COVID-19 ON 8/22/2020. INITIAL SYMPOTOMS ON THE 22ND WAS 100.9 F, MILD CHILLS, MILD HEADACHE, MODERATE LOSS OF SMELL, MILD COUGH, MILD BODY ACHES. NO MEDS TAKEN. 23RD TEMP WAS 99, TOOK TYLENOL 650 MG ONCE, 24 TEMP 98, MILD BODY ACHES, TYLENOL 650 MG ONCE IN MORNING. IN AFTERNOON WENT TO ILLNESS VISIT AT CLINIC SO DAY 1 FOR STUDY OBSERVATION IS DAY 3 OF INFECTION. Illness Visit D1 swab sent to Viracor and tested positive.' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:58:10
Query 'PV Query: Please add subject's medical history (prior to Day 1) to medical history eCRF. If none, please state so.' answered with 'none to add' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:06:00
User opened query 'PV Query: Please provide results of additional SARS-CoV-2 PCR tests (if and when performed), including Day 1 results.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 18:15:13
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)	27 Aug 2020 18:13:46
User opened query 'PV Query: Please confirm if hypertension and seasonal allergies were part of subject's medical history or were considered as AEs. Please report them accordingly in EDC.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 18:08:49
User opened query 'PV Query: Please add subject's medical history (prior to Day 1) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 18:08:29

US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Narrative

Audit	User	Time (GMT)
User entered 'Partificpant contacted us on 8/24/2020 to tell us he had symptoms and tested positive for Covid-19 on 8/22/2020. Initial sympotoms on the 22nd was 100.9 F, mild chills, mild headache, moderate loss of smell, mild cough, mild body aches. No meds taken. 23rd temp was 99, took Tylenol 650 mg once, 24 temp 98, mild body aches, Tylenol 650 mg once in morning. in afternoon went to illness visit at clinic so day 1 for study observation is day 3 of infection.' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:34:29
User opened query 'Per ETRTR: COVID + Narrative should describe clinical course of events, dates, times, treatments (include in ConMeds CRF) and any other assessments which help explain the event. Please add as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 15:44:36
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

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US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '0'	System	24 Aug 2020 14:25:38

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US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	24 Aug 2020 14:25:38

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US3522042
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:50:46
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22

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US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 11 Aug 2021 22:50:46
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:07
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:46:03

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US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 13:49:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 13:49:11
Data point term sent to Coder	System	07 Aug 2020 13:48:01
User entered 'hydrochlorothiazide'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

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US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

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US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered 'hypertension'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

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US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered '12.5'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered 'mg (mg)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

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US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered 'once daily (QD)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

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US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered 'Oral (ORAL)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

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US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

FDA-CBER-2022-1614-0809734

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:25:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'All concomitant medications are recorded for this subject.' (Site from System).	Jelena Verkler (b) (4) (b) (4)	10 Aug 2020 16:19:41
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 14:57:26
User entered 'Un UNK 2012'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

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US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

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US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

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US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

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US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	07 Aug 2020 13:47:25

FDA-CBER-2022-1614-0809740

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	07 Aug 2020 13:47:25

FDA-CBER-2022-1614-0809741

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:50:46
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '804 (804)'	System	07 Aug 2020 13:47:25

FDA-CBER-2022-1614-0809742

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 13:51:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 13:51:16
Data point term sent to Coder	System	07 Aug 2020 13:49:01
User entered 'loratadine'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

FDA-CBER-2022-1614-0809743

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

FDA-CBER-2022-1614-0809744

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered 'seasonal allergies'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered '10'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

FDA-CBER-2022-1614-0809746

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered 'mg (mg)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

FDA-CBER-2022-1614-0809747

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

FDA-CBER-2022-1614-0809748

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered 'once daily (QD)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

FDA-CBER-2022-1614-0809750

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered 'Oral (ORAL)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

FDA-CBER-2022-1614-0809751

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

FDA-CBER-2022-1614-0809752

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

FDA-CBER-2022-1614-0809753

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered '1'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

FDA-CBER-2022-1614-0809754

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

FDA-CBER-2022-1614-0809756

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	07 Aug 2020 13:48:29

FDA-CBER-2022-1614-0809758

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	07 Aug 2020 13:48:29

FDA-CBER-2022-1614-0809759

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:50:46
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '804 (804)'	System	07 Aug 2020 13:48:29

FDA-CBER-2022-1614-0809760

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:50:46
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
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)	30 Oct 2020 11:58:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 11:58:52
Data point term sent to Coder	System	30 Oct 2020 11:57:51
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 11:57:25
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)	30 Oct 2020 11:56:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 11:56:51
Data point term sent to Coder	System	30 Oct 2020 11:55:50
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 11:54:52
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)	26 Aug 2020 15:27:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:27:43
Data point term sent to Coder	System	26 Aug 2020 15:26:50
User entered 'Tylenol'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:50:46
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User closed query 'Per DM CLR: Prophylaxis = YES. Please review response for this indication as there is an AE recorded that matches this medication and used within the same timeframe. Please correct response to "No" in prophylaxis field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 11:26:53
Query 'Per DM CLR: Prophylaxis = YES. Please review response for this indication as there is an AE recorded that matches this medication and used within the same timeframe. Please correct response to "No" in prophylaxis field as appropriate. ' answered with 'updated' (Site from DM).	Jelena Verkler (b) (4) (b) (4)	06 Oct 2020 16:29:48
User entered 'No (N)' reason for change: Data Entry Error	Jelena Verkler (b) (4) (b) (4)	06 Oct 2020 16:29:02
User opened query 'Per DM CLR: Prophylaxis = YES. Please review response for this indication as there is an AE recorded that matches this medication and used within the same timeframe. Please correct response to "No" in prophylaxis field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 14:21:10
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

FDA-CBER-2022-1614-0809762

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:50:46
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered 'Symptomatic COVID-19' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 11:57:25
User entered 'FEVER/ Body Aches' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 11:54:52
User entered 'Fever'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

FDA-CBER-2022-1614-0809763

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:50:46
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered '650'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

FDA-CBER-2022-1614-0809764

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:50:46
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:50:46
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

FDA-CBER-2022-1614-0809766

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:50:46
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered 'once daily (QD)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

FDA-CBER-2022-1614-0809767

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:50:46
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

FDA-CBER-2022-1614-0809768

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:50:46
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

FDA-CBER-2022-1614-0809769

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:50:46
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

FDA-CBER-2022-1614-0809770

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:50:46
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered '23 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

FDA-CBER-2022-1614-0809771

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:50:46
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered '0'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

FDA-CBER-2022-1614-0809772

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:50:46
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:50:46
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered '24 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

FDA-CBER-2022-1614-0809774

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Fever in eDiary within this timeframe and AE indicates this condition is an Unsolicited event. Review response if this should be updated to "No" as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:24:34
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Fever in eDiary within this timeframe and AE indicates this condition is an Unsolicited event. Review response if this should be updated to "No" as appropriate.' answered with 'updated' (Site from DM).	Jelena Verkler (b) (4) (b) (4)	06 Oct 2020 16:29:54
User entered 'No (N)' reason for change: Data Entry Error	Jelena Verkler (b) (4) (b) (4)	06 Oct 2020 16:29:09
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Fever in eDiary within this timeframe and AE indicates this condition is an Unsolicited event. Review response if this should be updated to "No" as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 14:21:40
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:50:46
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	26 Aug 2020 15:26:18

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US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:50:46
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '1'	System	26 Aug 2020 15:26:18

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US3522042
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:50:46
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User entered '804 (804)'	System	26 Aug 2020 15:26:18

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US3522042
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 11 Aug 2021 22:50:46
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:44:52

US3522042
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 11 Aug 2021 22:50:46
Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered '22 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 15:55:59

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US3522042
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 11 Aug 2021 22:50:46
Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'Due to SARS-COV-2 (COVID)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 15:55:59

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US3522042

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:50:46

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)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered empty.	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 15:55:59

US3522042
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:50:46
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered '24 Dec 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	29 Dec 2020 19:33:57
User entered '23 Dec 2020'	Sharon Mathys (b) (4) (b) (4)	29 Dec 2020 19:33:46

FDA-CBER-2022-1614-0809783

US3522042
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:50:46
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User closed query 'Per CDM RQ: Reason for discontinuation=Other , However for AE #1, Action taken with Investigational product is marked as "Investigational product withdrawn", Please review , reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 04:34:59
Query 'Per CDM RQ: Reason for discontinuation=Other , However for AE #1, Action taken with Investigational product is marked as "Investigational product withdrawn", Please review , reconcile and update accordingly.' answered with 'Please see previous query response. Getting Sars-COV-2 causes withdrawal of IP if found before Dose 2 and does not preclude continuation in study. Do not reopen query unless there is another option for that AE to show that we did not give IP dose 2 due to infection.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	13 Jan 2021 14:27:25
User opened query 'Per CDM RQ: Reason for discontinuation=Other , However for AE #1, Action taken with Investigational product is marked as "Investigational product withdrawn", Please review , reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 08:42:03
User closed query 'Per CDM: Reason for discontinuation=Other , However for AE #1, Action taken with Investigational product is marked as "Investigational product withdrawn", Please review , reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 08:42:03
Query 'Per CDM: Reason for discontinuation=Other , However for AE #1, Action taken with Investigational product is marked as "Investigational product withdrawn", Please review , reconcile and update accordingly.' answered with 'Investigational product withdrawn per protocol due to sars-cov2 infection.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	11 Jan 2021 18:22:03
User opened query 'Per CDM: Reason for discontinuation=Other , However for AE #1, Action taken with Investigational product is marked as "Investigational product withdrawn", Please review , reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 09:40:20

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US3522042
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:50:46
Reason for discontinuation

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	29 Dec 2020 19:33:46

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US3522042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:50:46

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)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered 'WITHDREW TO RECEIVE EUA APPROVED COVID-19 VACCINE'	Sharon Mathys (b) (4) (b) (4)	29 Dec 2020 19:33:46

US3522042
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:50:46
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered empty.	Sharon Mathys (b) (4) (b) (4)	29 Dec 2020 19:33:46

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US3522042
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:50:46
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered empty.	Sharon Mathys (b) (4) (b) (4)	29 Dec 2020 19:33:46

FDA-CBER-2022-1614-0809788

US3522042
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:50:46
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered empty.	Sharon Mathys (b) (4) (b) (4)	29 Dec 2020 19:33:46

FDA-CBER-2022-1614-0809789

US3522042
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:50:46
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:25
User entered empty.	Sharon Mathys (b) (4) (b) (4)	29 Dec 2020 19:33:46

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'USA-US131-2020-MRNA-1273-P301000001'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809791

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809792

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

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US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Marcus'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

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US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Kilgore'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Zervos'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6) (b) (6) '	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '2799 West Grand Blvd'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809801

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6) '	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Detroit'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'MI'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Michigan'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809803

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '48202'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:13:21
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:18:03
Un-reviewed for Safety.	System	15 Sep 2020 22:12:16
User entered 'US' (non-conformant).	System	15 Sep 2020 22:12:16
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	03 Sep 2020 14:53:15
Un-reviewed for Safety.	System	31 Aug 2020 12:52:28
User entered 'US' (non-conformant).	System	31 Aug 2020 12:52:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '01' reason for change: Data Entry Error	mayur ramesh (b) (4) (b) (4)	29 Aug 2020 17:44:02
User entered 'US' (non-conformant).	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:19:59
User entered 'U.' (non-conformant).	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:19:06
User entered 'US' (non-conformant).	System	24 Aug 2020 16:23:52

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '4'	System	20 Sep 2020 21:13:32
User entered '3'	System	15 Sep 2020 22:12:16
User entered '2'	System	31 Aug 2020 12:52:28
User entered '1'	System	24 Aug 2020 16:23:52

FDA-CBER-2022-1614-0809806

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'USA-US131-2020-MRNA-1273-P301000001'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809807

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809808

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809809

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809811

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809814

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Marcus'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Kilgore'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Zervos'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6) (b) (6) '	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '2799 West Grand Blvd'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6) '	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Detroit'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809818

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'MI'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Michigan'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809819

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '48202'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:13:21
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:18:03
Un-reviewed for Safety.	System	15 Sep 2020 22:12:16
User entered 'US' (non-conformant).	System	15 Sep 2020 22:12:16
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	03 Sep 2020 14:53:15
Un-reviewed for Safety.	System	31 Aug 2020 12:52:28
User entered 'US' (non-conformant).	System	31 Aug 2020 12:52:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '01' reason for change: Data Entry Error	mayur ramesh (b) (4) (b) (4)	29 Aug 2020 17:44:02
User entered 'US' (non-conformant).	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:19:59
User entered 'U.' (non-conformant).	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:19:06
User entered 'US' (non-conformant).	System	24 Aug 2020 16:23:52

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '4'	System	20 Sep 2020 21:13:32
User entered '3'	System	15 Sep 2020 22:12:16
User entered '2'	System	31 Aug 2020 12:52:28
User entered '1'	System	24 Aug 2020 16:23:52

FDA-CBER-2022-1614-0809822

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form (1)
Generated On: 11 Aug 2021 22:50:46
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
User entered '24/Aug/2020 12:23'	System	24 Aug 2020 16:23:52

FDA-CBER-2022-1614-0809823

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:50:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '1'	(b) (4), (b) (6)	24 Aug 2020 16:23:52

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'USA-US131-2020-MRNA-1273-P301000001'	System	24 Aug 2020 16:20:43

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809826

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809827

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809828

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809830

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Marcus'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Kilgore'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Zervos'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809834

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6) (b) (6) '	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '2799 West Grand Blvd'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809835

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6) '	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Detroit'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809836

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'MI'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Michigan'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809837

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '48202'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809838

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:13:21
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:18:03
Un-reviewed for Safety.	System	15 Sep 2020 22:12:16
User entered 'US' (non-conformant).	System	15 Sep 2020 22:12:16
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	03 Sep 2020 14:53:15
Un-reviewed for Safety.	System	31 Aug 2020 12:52:28
User entered 'US' (non-conformant).	System	31 Aug 2020 12:52:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '01' reason for change: Data Entry Error	mayur ramesh (b) (4) (b) (4)	29 Aug 2020 17:44:02
User entered 'US' (non-conformant).	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:19:59
User entered 'U.' (non-conformant).	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:19:06
User entered 'US' (non-conformant).	System	24 Aug 2020 16:23:52

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '4'	System	20 Sep 2020 21:13:32
User entered '3'	System	15 Sep 2020 22:12:16
User entered '2'	System	31 Aug 2020 12:52:28
User entered '1'	System	24 Aug 2020 16:23:52

FDA-CBER-2022-1614-0809840

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form (2)
Generated On: 11 Aug 2021 22:50:46
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
User entered '31/Aug/2020 08:52'	System	31 Aug 2020 12:52:28

FDA-CBER-2022-1614-0809841

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:50:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
User entered '1'	(b) (4), (b) (6)	31 Aug 2020 12:52:28

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'USA-US131-2020-MRNA-1273-P301000001'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809843

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809844

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809845

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809846

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809848

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809849

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

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FDA-CBER-2022-1614-0809850

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Marcus'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809851

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Kilgore'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Zervos'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809852

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6) (b) (6) '	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '2799 West Grand Blvd'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809853

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6) '	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Detroit'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809854

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'MI'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Michigan'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809855

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '48202'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809856

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:13:21
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:18:03
Un-reviewed for Safety.	System	15 Sep 2020 22:12:16
User entered 'US' (non-conformant).	System	15 Sep 2020 22:12:16
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	03 Sep 2020 14:53:15
Un-reviewed for Safety.	System	31 Aug 2020 12:52:28
User entered 'US' (non-conformant).	System	31 Aug 2020 12:52:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '01' reason for change: Data Entry Error	mayur ramesh (b) (4) (b) (4)	29 Aug 2020 17:44:02
User entered 'US' (non-conformant).	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:19:59
User entered 'U.' (non-conformant).	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:19:06
User entered 'US' (non-conformant).	System	24 Aug 2020 16:23:52

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '4'	System	20 Sep 2020 21:13:32
User entered '3'	System	15 Sep 2020 22:12:16
User entered '2'	System	31 Aug 2020 12:52:28
User entered '1'	System	24 Aug 2020 16:23:52

FDA-CBER-2022-1614-0809858

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form (3)
Generated On: 11 Aug 2021 22:50:46
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
User entered '15/Sep/2020 18:12'	System	15 Sep 2020 22:12:16

FDA-CBER-2022-1614-0809859

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:50:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:13:21
User entered '1'	(b) (4), (b) (6)	15 Sep 2020 22:12:16

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'USA-US131-2020-MRNA-1273-P301000001'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809861

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809862

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809864

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809866

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

FDA-CBER-2022-1614-0809868

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Marcus'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809869

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Kilgore'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Zervos'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809870

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6) (b) (6) '	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '2799 West Grand Blvd'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809871

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6) '	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Detroit'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809872

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'MI'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Michigan'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809873

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '48202'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:18:46

FDA-CBER-2022-1614-0809874

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:13:21
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:18:03
Un-reviewed for Safety.	System	15 Sep 2020 22:12:16
User entered 'US' (non-conformant).	System	15 Sep 2020 22:12:16
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	03 Sep 2020 14:53:15
Un-reviewed for Safety.	System	31 Aug 2020 12:52:28
User entered 'US' (non-conformant).	System	31 Aug 2020 12:52:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '01' reason for change: Data Entry Error	mayur ramesh (b) (4) (b) (4)	29 Aug 2020 17:44:02
User entered 'US' (non-conformant).	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:19:59
User entered 'U.' (non-conformant).	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 19:19:06
User entered 'US' (non-conformant).	System	24 Aug 2020 16:23:52

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:50:46
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
User entered '4'	System	20 Sep 2020 21:13:32
User entered '3'	System	15 Sep 2020 22:12:16
User entered '2'	System	31 Aug 2020 12:52:28
User entered '1'	System	24 Aug 2020 16:23:52

FDA-CBER-2022-1614-0809876

US3522042
Folder: SAE USA-US131-2020-MRNA-1273-P301000001
Form: Safety Report Form (4)
Generated On: 11 Aug 2021 22:50:46
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
User entered '20/Sep/2020 17:13'	System	20 Sep 2020 21:13:32

FDA-CBER-2022-1614-0809877

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:50:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:33:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
User entered '1'	(b) (4), (b) (6)	20 Sep 2020 21:13:32