

US3522297 (Prod: Henry Ford Health System)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:52:01

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US3522297

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

[Participant ID](#)

US3522297

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

US3522297

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:45:33

Generated On: 11 Aug 2021 22:52:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3522297

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 15:45:33

Generated On: 11 Aug 2021 22:52:01

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	63
Age Units	YEARS
Age (Derived)	63
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input checked="" type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 15:45:33

Generated On: 11 Aug 2021 22:52:01

Date of Informed Consent (*dd MMM yyyy*) 21 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

US3522297

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 15:45:33

Generated On: 11 Aug 2021 22:52:01

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 15:45:33

Generated On: 11 Aug 2021 22:52:01

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 15:45:33

Generated On: 11 Aug 2021 22:52:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:45 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 14:45
Height (<i>xxx.x</i>)	70 in
Weight (<i>xxx.x</i>)	215 lb
BMI (<i>xxx.x</i>)	30.91379 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 15:45:33

Generated On: 11 Aug 2021 22:52:01

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 15:45:33

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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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 15:45:33

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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	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 107148

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

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

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

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

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

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

Liver Disease Yes No

Human Immunodeficiency Virus (HIV) infection Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:45 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 14:45
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	16:20 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 16:20
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Was the physical examination performed?

Yes

No

Date of examination (*dd MMM yyyy*) _____

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

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) 21 AUG 2020

What was the treatment time? (00:00-23:59) 15:50 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 15:50

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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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 21 AUG 2020

Collection time (*00:00-23:59*) 14:55 (24 HR)

Collection date and time (derived) 21 AUG 2020 14:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Collection date (<i>dd MMM yyyy</i>)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:57	21 AUG 2020 14:57
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

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 21 AUG 2020 16:16

PC Open Date & Time 21 AUG 2020 16:10

PC Close Date & Time 21 AUG 2020 18:40

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

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** 97.2 °F

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

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

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

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

PC Time Stamp 22 AUG 2020 08:56

PC Open Date & Time 21 AUG 2020 19:35

PC Close Date & Time 22 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:52:01

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 97.4 °F

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

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

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

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

PC Time Stamp 23 AUG 2020 09:27

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:52:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 AUG 2020 16:48
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:52:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	24 AUG 2020 23:44
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:52:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	25 AUG 2020 21:32
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:52:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	26 AUG 2020 19:28
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:52:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	28 AUG 2020 08:26
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

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

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

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

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

- Yes
- No

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

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

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

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

PC Open Date & Time

21 AUG 2020 16:10

PC Close Date & Time

21 AUG 2020 18:40

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

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	22 AUG 2020 08:58
PC Open Date & Time	21 AUG 2020 19:35
PC Close Date & Time	22 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:01

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

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

1

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

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

Yes

No

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

1

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

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

23 AUG 2020 09:29

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:52:01

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	23 AUG 2020 16:49
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:52:01

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

24 AUG 2020 23:44

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:52:01

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	25 AUG 2020 21:33
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:52:01

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

26 AUG 2020 19:29

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:52:01

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	28 AUG 2020 08:25
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

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

No

Yes

PC Time stamp

PC Open Date & Time

21 AUG 2020 16:10

PC Close Date & Time

21 AUG 2020 18:40

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

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

No

Yes

PC Time stamp	22 AUG 2020 08:59
PC Open Date & Time	21 AUG 2020 19:35
PC Close Date & Time	22 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:01

	Yes <input type="checkbox"/>
PC Time stamp	23 AUG 2020 09:30
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:01

	Yes <input type="checkbox"/>
PC Time stamp	23 AUG 2020 16:50
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:01

	Yes <input type="checkbox"/>
PC Time stamp	24 AUG 2020 23:45
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:01

	Yes <input type="checkbox"/>
PC Time stamp	25 AUG 2020 21:34
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:01

	Yes <input type="checkbox"/>
PC Time stamp	26 AUG 2020 19:29
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:01

	Yes <input type="checkbox"/>
PC Time stamp	28 AUG 2020 08:26
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3522297

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 28 AUG 2020

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

Comments NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK. PATIENT TOOK ASPIRIN
FOR JOINT PAIN

If Contact Not Made, please provide Comments

US3522297

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522297

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Was Contact Attempted? Yes No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 04 SEP 2020

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

Comments NO ONGOING OR NEW AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE.

If Contact Not Made, please provide Comments

US3522297

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522297

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE

If Contact Not Made, please provide Comments

US3522297

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522297

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

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 _____

US3522297

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

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.

US3522297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

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? _____

US3522297

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Was the sample collected? Yes
No

Collection date (dd MMM yyyy) _____

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

Collection date and time (derived) _____

US3522297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Collection date (*dd MMM yyyy*)

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

US3522297

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522297

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments TAKEN OVER BY DAILY
TELEMEDICINE ILLNESS
VISITS.
If Contact Not Made, please provide Comments

US3522297

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522297

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 02 OCT 2020

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

Comments TAKEN OVER BY DAILY
TELEMEDICINE ILLNESS VISITS
WITH STUDY PHYSICIAN

If Contact Not Made, please provide Comments

US3522297

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522297

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

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

PATIENT WAS CONFIRMED
COVID-19 POSITIVE, HAS BEEN
HAVING TELEMEDICINE VISITS
WITH THE STUDY DOCTOR
SINCE.

US3522297

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522297

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT3

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3522297

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

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.

US3522297

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Was the sample collected? Yes
No

Collection date (dd MMM yyyy) _____

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

Collection date and time (derived) _____

US3522297

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:41:18

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 OCT 2020 18:54:49
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 OCT 2020 12:32:08
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 NOV 2020 06:50:29
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 08:18:58
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 12:02:30
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 19:26:44
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 09:13:28
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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 20 DEC 2020 10:04:12

Patient Cloud Open Date & Time 20 DEC 2020 00:01

Patient Cloud Close Date & Time 24 DEC 2020 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 DEC 2020 12:01:33
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 JAN 2021 12:31:26
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 12:59:56
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 08:50:18
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 159

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

No

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

26 JAN 2021 10:08:23

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 166

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

No

Yes

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

No

Yes

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

Date and time of submission 31 JAN 2021 10:51:58

Patient Cloud Open Date & Time 31 JAN 2021 00:01

Patient Cloud Close Date & Time 04 FEB 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 173

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

No

Yes

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

No

Yes

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

Date and time of submission 07 FEB 2021 00:03:03

Patient Cloud Open Date & Time 07 FEB 2021 00:01

Patient Cloud Close Date & Time 11 FEB 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 180

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 FEB 2021 12:03:41
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 194

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

No

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

01 MAR 2021 09:44:25

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 MAR 2021 17:26:43
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 MAR 2021 12:46:28
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 00:20:58
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 MAR 2021 08:01:39
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 229

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

No

Yes

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

No

Yes

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

Date and time of submission 06 APR 2021 12:02:01

Patient Cloud Open Date & Time 04 APR 2021 00:01

Patient Cloud Close Date & Time 08 APR 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 APR 2021 01:11:55
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 APR 2021 12:40:59
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 APR 2021 07:39:40
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAY 2021 00:09:52
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 264

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

Patient Cloud Open Date & Time	20 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 320

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#) 08 JUL 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

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22 JUL 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

Patient Cloud Open Date & Time	25 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

Patient Cloud Open Date & Time	08 AUG 2021 00:01
Patient Cloud Close Date & Time	12 AUG 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

Patient Cloud Open Date & Time	12 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 07 OCT 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 14 OCT 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 28 OCT 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

Patient Cloud Open Date & Time	14 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

Patient Cloud Open Date & Time	09 JAN 2022 00:01
Patient Cloud Close Date & Time	13 JAN 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#) 03 FEB 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

Patient Cloud Open Date & Time	06 FEB 2022 00:01
Patient Cloud Close Date & Time	10 FEB 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 600

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

Patient Cloud Open Date & Time	10 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 614

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

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04 AUG 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

Patient Cloud Open Date & Time	14 AUG 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 740

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

Patient Cloud Open Date & Time	11 SEP 2022 00:01
Patient Cloud Close Date & Time	15 SEP 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 13 OCT 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

DAY 796

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

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

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

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

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

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

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 27 OCT 2022 23:59

US3522297

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:52:01

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 10:23:49

US3522297

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:45:33

Generated On: 11 Aug 2021 22:52:01

Was Contact Attempted? Yes No

Date of Contact or Contact Attempt (dd MMM yyyy) 13 NOV 2020

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

Comments NO ONGOING OR NEW AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS. MOTHER IN LAW CAME DOWN WITH COVID 19 ON 29 OCT 2020. HAS BEEN TAKING CARE OF HER SINCE 6NOV

US3522297

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:45:33

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522297

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 17 DEC 2020

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

Comments NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE

If Contact Not Made, please provide Comments

US3522297

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522297

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Was Contact Attempted? Yes No

Date of Contact or Contact Attempt (dd MMM yyyy) 15 JAN 2021

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

Comments "NO ONGOING OR NEW AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE OR PREGNANCY RISK."

If Contact Not Made, please provide Comments

US3522297

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522297

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 16 FEB 2021

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

Comments NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE

If Contact Not Made, please provide Comments

US3522297

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522297

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 11:38:43

Generated On: 11 Aug 2021 22:52:01

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 26 MAR 2021

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

Folder OID VISIT4

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 11:38:43

Generated On: 11 Aug 2021 22:52:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	08:18 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 08:18
Temperature (<i>xxx.x</i>)	97.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	51 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522297

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 11:38:43

Generated On: 11 Aug 2021 22:52:01

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

26 MAR 2021

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

US3522297

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 11:38:43

Generated On: 11 Aug 2021 22:52:01

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 26 MAR 2021

Collection time (*00:00-23:59*) 08:30 (24 HR)

Collection date and time (derived) 26 MAR 2021 08:30

US3522297

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 11:38:43

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522297

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 19 Apr 2021 19:03:52

Generated On: 11 Aug 2021 22:52:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 19 APR 2021

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

Comments NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK

If Contact Not Made, please provide Comments

US3522297

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 19:03:51

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522297

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

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 _____

US3522297

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

Date of Contact	18 SEP 2020
Time of Contact	08:18
Date and Time of Contact (derived)	18 SEP 2020 08:18
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/> Clinical Visit - Unscheduled <input type="checkbox"/> Safety Call <input checked="" type="checkbox"/> Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	17 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	98.1 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 19 SEP 2020

Assessment Not Done False

O2 Saturation 98 %

O2 Saturation Units %

Temperature 99.1 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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 20 SEP 2020

Assessment Not Done False

O2 Saturation 99 %

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	21 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.4 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 22 SEP 2020

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 96.2 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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 23 SEP 2020

Assessment Not Done False

O2 Saturation 98 %

O2 Saturation Units %

Temperature 96.8 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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	24 SEP 2020
------	-------------

Assessment Not Done	False
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O2 Saturation	95 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.8 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 25 SEP 2020

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 97.1 F

Chills

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Cough

None	<input type="radio"/>
Mild	<input checked="" type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Shortness of Breath

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	26 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	96.8 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 27 SEP 2020

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 97.1 F

Chills

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Cough

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Shortness of Breath

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	28 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.3 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	29 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.5 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	30 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.3 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 1 OCT 2020

Assessment Not Done False

O2 Saturation 99 %

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	2 OCT 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.2 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	3 OCT 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.1 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	4 OCT 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.8 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	05 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	96.6 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	6 OCT 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.8 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	07 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.6 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 08 OCT 2020

Assessment Not Done False

O2 Saturation 96 %

O2 Saturation Units %

Temperature 98.4 F

Chills

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Cough

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Shortness of Breath

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

Symptom Day

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	18 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Data signed: (b) (4) 19 Mar 2021 18:13:02

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

Date of Visit 18 SEP 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 18 SEP 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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes
No

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes
No

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes
No

If Yes, provide:

Start Date _____

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 _____

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

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 _____

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

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 _____

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 12 Mar 2021 15:21:48

Generated On: 11 Aug 2021 22:52:01

[Generate Next COVID-19 Assessment](#)

Yes

No

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 28 Apr 2021 22:32:38

Generated On: 11 Aug 2021 22:52:01

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	20 SEP 2020
Day 5	Yes	22 SEP 2020
Day 7	Yes	24 SEP 2020
Day 9	Yes	26 SEP 2020
Day 14	Yes	1 OCT 2020
Day 21	Yes	08 OCT 2020
Day 28	No	

US3522297

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:50 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 15:50
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3522297

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3522297

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

Date of Collection

18 SEP 2020

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:15 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 08:15
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	58 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
	NA (COVID-19 Negative) <input type="radio"/>

Date of Collection	16 OCT 2020
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US3522297

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 22 JAN 2021

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

Folder OID UNBLND_DECIDE

US3522297

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 18:13:03

Generated On: 11 Aug 2021 22:52:01

Date of updated informed consent (<i>dd MMM yyyy</i>)	22 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	22 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3522297

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Height	_____
Weight	_____
BMI (xxx.x)	_____

US3522297

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	08:20 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 08:20
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3522297

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 09:40
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3522297

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

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

22 JAN 2021

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

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 22 JAN 2021

What was the treatment time? (00:00-23:59) 09:10 (24 HR)

Treatment Date and Time (derived) 22 JAN 2021 09:10

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

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 22 JAN 2021

Collection time (*00:00-23:59*) 08:25 (24 HR)

Collection date and time (derived) 22 JAN 2021 08:25

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 22 JAN 2021

Collection time (*00:00 - 23:59*) 08:30

Collection Date and Time (derived) 22 JAN 2021 08:30

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522297

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:45:33

Generated On: 11 Aug 2021 22:52:01

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 29 JAN 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments CALL COMPLETED

If Contact Not Made, please provide Comments

US3522297

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:45:33

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3522297

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 19 FEB 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID OLD29

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	08:31 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 08:31
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	09:16 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 09:16
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3522297

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

19 FEB 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3522297

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 19 FEB 2021

What was the treatment time? (00:00-23:59) 08:46 (24 HR)

Treatment Date and Time (derived) 19 FEB 2021 08:46

Which arm was used to give treatment? Left Arm
Right Arm

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3522297

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522297

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:45:33

Generated On: 11 Aug 2021 22:52:01

Was Contact Attempted? Yes No

Date of Contact or Contact Attempt (dd MMM yyyy) 01 MAR 2021

Please select one status for the follow-up contact Contact Made Contact Not Made

Comments SEE SOURCE NOTE. NO ONGOING OR NEW AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE OR PREGNANCY RISK.

If Contact Not Made, please provide Comments

US3522297

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:45:33

Generated On: 11 Aug 2021 22:52:01

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3522297

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 11:38:43

Generated On: 11 Aug 2021 22:52:01

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 26 MAR 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID OLD57

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 11:38:43

Generated On: 11 Aug 2021 22:52:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	08:18 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 08:18
Temperature (<i>xxx.x</i>)	97.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	51 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522297

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 11:38:43

Generated On: 11 Aug 2021 22:52:01

Was the physical examination performed?

Yes

No

Date of examination (*dd MMM yyyy*)

26 MAR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3522297

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 11:38:43

Generated On: 11 Aug 2021 22:52:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	26 MAR 2021
Collection time (<i>00:00-23:59</i>)	08:30 (24 HR)
Collection date and time (derived)	26 MAR 2021 08:30

US3522297

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

AEID USA-US131-2020-MRNA-1273-P30
1000004

Adverse event SYMPTOMATIC COVID-19
INFECTION

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) 18 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 26 SEP 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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

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

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

ON MONDAY, SEPTEMBER 7TH.
PT'S WIFE STARTED TO FEEL
ILL AND SICK, SO SHE LATER
WENT TO GET TESTED ON
SEPTEMBER 8TH. RESULTS
CAME BACK ON THE 10TH
STATING NEGATIVE. SHE FELT
BETTER ON SATURDAY (12TH).
SUNDAY(13TH) PT AND WIFE
WENT TO GET DINNER AT AN
OUTDOOR RESTAURANT. ON
MONDAY (14TH) PT'S WIFE
LOST HER SENSE OF SMELL
AND WENT TO GET ANOTHER
TEST SAME DAY. COVID TEST
RESULT CAME BACK POSITIVE
ON THE 16TH. THURSDAY
(17TH) MORNING PATIENT GOT
TESTED, RESULTS CAME BACK
POSITIVE FRIDAY (18TH).
SLIGHT COUGH FOR 3 DAYS,
TEMPERATURE WAS HIGHEST
AT 100F ON FRIDAY(18TH).
MONDAY (21ST) PT LOST SENSE
OF SMELL AND TASTE,
STARTED FEELING BETTER BY
FRIDAY (25TH). ON 26TH/27TH,
PT REPORTS HAVING
SENSATIONS INSIDE HIS NOSE,
AS HIS SENSE OF TASTE AND
SMELL WAS FULLY COMING
BACK. PATIENT REPORTS
HEADACHES, AND FATIGUE,
NO SOB. PATIENT TOOK 1
ASPIRIN DAILY (325 MG) FROM
9/18 - 9/26. PATIENT
QUARANTINED IMMEDIATELY
AFTER GETTING TEST
RESULTS. NO CURRENT
SYMPTOMS OTHER THAN
SLIGHT FATIGUE.

Serious Adverse Event Derived (CSA Programming Field Only) 0

Medically Attended AE Derived (CSA Programming Field Only) 0

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US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

Admitted to ICU Derived (CSA Programming Field Only)

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

Were any prior/concomitant medications and/or vaccinations taken?

Yes

No

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication JOINT ACHES IN SEVERAL JOINTS

Dose per administration 325

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 22 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 23 AUG 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication SYMPTOMATIC COVID-19
INFECTION

Dose per administration 325

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

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EAB) (1725)

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US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	18 SEP 2020
--------------------------	-------------

Start date completely unknown	False
-------------------------------	-------

Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

If not Ongoing, End date (dd MMM yyyy)	26 SEP 2020
----------------------------------------	-------------

Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

Separate Dosage Number (derived)	1
----------------------------------	---

Interval Dosage Unit Number (derived)	1
---------------------------------------	---

Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

US3522297

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 15:45:26

Generated On: 11 Aug 2021 22:52:01

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3522297

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

Date of dosing discontinuation (dd MMM yyyy) 18 SEP 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 _____

US3522297

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:52:01

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

- AE (specify)
- SAE (specify)
- Complete
- Death
- Lost To Follow-up
- Physician decision (specify)
- Pregnancy
- Protocol deviation (specify)
- Study Terminated By Sponsor
- Withdrawal of consent by participant (specify)
- Other

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

- Adverse event
- Unknown
- Other

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

- Yes
 - No
 - Unknown
-

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

SAEID	USA-US131-2020-MRNA-1273-P30 1000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

SAEID	USA-US131-2020-MRNA-1273-P30 1000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	23/SEP/2020 07:48
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

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

SAEID	USA-US131-2020-MRNA-1273-P30 1000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	05/OCT/2020 10:30
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

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

SAEID	USA-US131-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	05/NOV/2020 22:14
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

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Mar 2021 15:45:28

Generated On: 11 Aug 2021 22:52:01

SAEID	USA-US131-2020-MRNA-1273-P30 1000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	18/NOV/2020 14:33
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

US3522297 (Prod: Henry Ford Health System)

US3522297

Form: Participant Creation

Generated On: 11 Aug 2021 22:52:01

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'US3522297'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 18:29:36

US3522297

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:39:16

US3522297

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 18:29:37

US3522297

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:39:16

US3522297

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User entered 'SCRN'	System	21 Aug 2020 18:39:16

US3522297

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:01

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered (b) (6) 1957'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 18:29:38

US3522297

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:01

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '63'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:01

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User entered 'YEARS'	System	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:01

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User entered '63'	System	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:01

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:01

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:01

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '1'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:01

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:01

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:01

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:01

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:01

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:01

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:52:01

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:52:01

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:52:01

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User entered 'Aug 2020'	System	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:52:01

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User entered '2020'	System	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:52:01

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Amendment 2 (2)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:52:01

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:52:01

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:52:01

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:52:01

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:52:01

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 18:29:37

US3522297

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:52:01

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User entered '1'	System	21 Aug 2020 18:40:33

US3522297

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:52:01

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:40:33

US3522297

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:52:01

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:40:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User closed query 'Per CDM: Per CCG, Time of assessment should be entered in 24- hour clock format (HH:MM). Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 03:52:42
Query 'Per CDM: Per CCG, Time of assessment should be entered in 24- hour clock format (HH:MM). Please review and update accordingly. ' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	05 Nov 2020 14:36:07
User entered '14:45' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	05 Nov 2020 14:36:02
User entered '14:38' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	05 Nov 2020 14:34:31
User opened query 'Per CDM: Per CCG, Time of assessment should be entered in 24- hour clock format (HH:MM). Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 11:34:09
User entered '2:38'	(b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User entered '21 Aug 2020 14:45'	System	05 Nov 2020 14:36:02
User entered '21 Aug 2020 14:38'	System	05 Nov 2020 14:34:31
User entered '21 Aug 2020 2:38'	System	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '70' in	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:41:38
DataPoint set to visible.	System	21 Aug 2020 18:40:33

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '215' lb	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:41:38
DataPoint set to visible.	System	21 Aug 2020 18:40:33

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
Amendment Manager: User entered '30.91379'	System	17 Sep 2020 00:18:58
User entered '30.9'	System	21 Aug 2020 18:41:38
DataPoint set to visible.	System	21 Aug 2020 18:40:33

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User entered 'kg/m2'	System	21 Aug 2020 18:41:38
DataPoint set to visible.	System	21 Aug 2020 18:40:33

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User entered 'bpm'	System	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User entered 'breaths/min'	System	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User entered 'mmHg'	System	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User entered 'mmHg'	System	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46

US3522297

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:41:48

US3522297

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:41:48

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

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)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

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)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

[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)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

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)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

[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)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

[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)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

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)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

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)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

[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)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

[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)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

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)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '1'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:52:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:30:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:43

US3522297

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:43

US3522297

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:43

US3522297

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered 'VISIT1'	System	21 Aug 2020 18:42:43

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:52:01

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 18:45:17

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:52:01

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '107148'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 18:45:17

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:52:01

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 18:45:17

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:52:01

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:53

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:52:01

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:53

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:52:01

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:53

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:52:01

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:53

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:52:01

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:42:53

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:52:01

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4)	05 Oct 2020 11:48:20
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:38:37
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:08:36

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '14:45' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:29:41
User entered '14:38' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 20:25:06
User entered '2:38'	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered '21 Aug 2020 14:45'	System	22 Oct 2020 18:29:41
User entered '21 Aug 2020 14:38'	System	21 Aug 2020 20:25:06
User entered '21 Aug 2020 2:38'	System	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'Temporal' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 18:51:52
User entered 'IR'	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '63'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered 'bpm'	System	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '15'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered 'breaths/min'	System	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '103'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered 'mmHg'	System	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '72'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered 'mmHg'	System	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:25:06
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:25:06
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '16:20' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 20:25:06
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered '21 Aug 2020 16:20'	System	21 Aug 2020 20:25:06
User entered empty.	System	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '97.9' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:25:06
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 20:25:06
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Temporal' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:25:06
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '60' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 20:25:06
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered 'bpm'	System	21 Aug 2020 20:25:06
User entered empty.	System	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '15' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 20:25:06
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered 'breaths/min'	System	21 Aug 2020 20:25:06
User entered empty.	System	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '116' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:25:06
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered 'mmHg'	System	21 Aug 2020 20:25:06
User entered empty.	System	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '72' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 20:25:06
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered 'mmHg'	System	21 Aug 2020 20:25:06
User entered empty.	System	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 18:52:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:47:46

US3522297

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 18:52:02
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 18:47:46

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '15:50'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered '21 Aug 2020 15:50'	System	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered 'ONCE'	System	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:03:59

US3522297

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:03:59

US3522297

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '14:55' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 19:51:43
User entered '2:55'	(b) (4), (b) (6)	21 Aug 2020 19:03:59

US3522297

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered '21 Aug 2020 14:55'	System	21 Aug 2020 19:51:43
User entered '21 Aug 2020 2:55'	System	21 Aug 2020 19:03:59

US3522297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:52:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:04:14

US3522297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:52:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Aug 2020 19:04:14

US3522297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:52:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:04:14

US3522297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:52:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '14:57' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 19:51:57
User entered '2:57'	(b) (4), (b) (6)	21 Aug 2020 19:04:14

US3522297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:52:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered '21 Aug 2020 14:57'	System	21 Aug 2020 19:51:57
User entered '21 Aug 2020 2:57'	System	21 Aug 2020 19:04:14

US3522297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:52:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Aug 2020 19:04:14

US3522297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:52:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:04:14

US3522297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:52:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:04:14

US3522297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:52:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	21 Aug 2020 19:04:14

US3522297

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:47:52

US3522297

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered '1'	System	21 Aug 2020 18:47:52

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-21T16:15:47', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'd1c218b6-b2ba-478d-920a-8d1855ace005' User entered 'Yes (Y)'	System	21 Aug 2020 20:16:30
	System	21 Aug 2020 20:16:30

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-21T16:16:10', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'd1c218b6-b2ba-478d-920a-8d1855ace005' User entered '97.9'	System	21 Aug 2020 20:16:30
	System	21 Aug 2020 20:16:30

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-21T16:16:17', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'd1c218b6-b2ba-478d-920a-8d1855ace005'	System	21 Aug 2020 20:16:30
User entered 'No (N)'	System	21 Aug 2020 20:16:30

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-21T16:16:25', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'd1c218b6-b2ba-478d-920a-8d1855ace005' User entered '21 Aug 2020 16:16'	System	21 Aug 2020 20:16:30
	System	21 Aug 2020 20:16:30

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '21 Aug 2020 16:10'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '21 Aug 2020 18:40'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:54:47', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '3c9edb8d-f8e5-4549-8bd3-582ecb0a4294' User entered 'Yes (Y)'	System	22 Aug 2020 12:56:21
	System	22 Aug 2020 12:56:21

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:55:33', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '3c9edb8d-f8e5-4549-8bd3-582ecb0a4294' User entered '97.2'	System	22 Aug 2020 12:56:21
	System	22 Aug 2020 12:56:21

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:55:41', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '3c9edb8d-f8e5-4549-8bd3-582ecb0a4294' User entered 'Yes (Y)'	System	22 Aug 2020 12:56:21
	System	22 Aug 2020 12:56:21

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Aspirin. Recorded' (Site from System).	(b) (4), (b) (6)	29 Aug 2020 18:20:13
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:55:55', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '3c9edb8d-f8e5-4549-8bd3-582ecb0a4294'	(b) (4), (b) (6)	28 Aug 2020 14:27:58
User entered '1'	System	22 Aug 2020 12:56:21
	System	22 Aug 2020 12:56:21
	System	22 Aug 2020 12:56:21

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:55:55', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '3c9edb8d-f8e5-4549-8bd3-582ecb0a4294' User entered '0'	System	22 Aug 2020 12:56:21
	System	22 Aug 2020 12:56:21

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:56:16', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '3c9edb8d-f8e5-4549-8bd3-582ecb0a4294' User entered '22 Aug 2020 08:56'	System	22 Aug 2020 12:56:21
	System	22 Aug 2020 12:56:21

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '21 Aug 2020 19:35'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 2'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:52:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:26:48', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'e0a4e043-017b-4da4-93f3-d9d2e61f0c2b' User entered 'Yes (Y)'	System	23 Aug 2020 13:27:30
	System	23 Aug 2020 13:27:30

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:52:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:26:56', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'e0a4e043-017b-4da4-93f3-d9d2e61f0c2b' User entered '97.4'	System	23 Aug 2020 13:27:30
	System	23 Aug 2020 13:27:30

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:52:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:27:04', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'e0a4e043-017b-4da4-93f3-d9d2e61f0c2b'	System	23 Aug 2020 13:27:30
User entered 'Yes (Y)'	System	23 Aug 2020 13:27:30

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:52:01

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Aspirin recorded' (Site from System).	(b) (4), (b) (6)	29 Aug 2020 18:19:47
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	28 Aug 2020 14:28:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:27:12', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'e0a4e043-017b-4da4-93f3-d9d2e61f0c2b'	System	23 Aug 2020 13:27:30
User entered '1'	System	23 Aug 2020 13:27:30

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:52:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:27:12', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'e0a4e043-017b-4da4-93f3-d9d2e61f0c2b' User entered '0'	System	23 Aug 2020 13:27:30
	System	23 Aug 2020 13:27:30

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:52:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:27:28', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'e0a4e043-017b-4da4-93f3-d9d2e61f0c2b' User entered '23 Aug 2020 09:27'	System	23 Aug 2020 13:27:30
	System	23 Aug 2020 13:27:30

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 3'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:52:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:48:08', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'a3896bc5-9d9a-4582-8560-446a224a6514' User entered 'Yes (Y)'	System	23 Aug 2020 20:48:38
	System	23 Aug 2020 20:48:38

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:52:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:48:16', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'a3896bc5-9d9a-4582-8560-446a224a6514' User entered '98.6'	System	23 Aug 2020 20:48:38
	System	23 Aug 2020 20:48:38

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:52:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:48:27', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'a3896bc5-9d9a-4582-8560-446a224a6514' User entered 'No (N)'	System	23 Aug 2020 20:48:38
	System	23 Aug 2020 20:48:38

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:52:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:48:34', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'a3896bc5-9d9a-4582-8560-446a224a6514' User entered '23 Aug 2020 16:48'	System	23 Aug 2020 20:48:38
	System	23 Aug 2020 20:48:38

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 4'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:52:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:44:04', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'd1f5ffe4-2814-42bb-88eb-627d3645912f' User entered 'Yes (Y)'	System	25 Aug 2020 03:44:26
	System	25 Aug 2020 03:44:26

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:52:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:44:13', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'd1f5ffe4-2814-42bb-88eb-627d3645912f' User entered '97.3'	System	25 Aug 2020 03:44:26
	System	25 Aug 2020 03:44:26

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:52:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:44:18', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'd1f5ffe4-2814-42bb-88eb-627d3645912f' User entered 'No (N)'	System	25 Aug 2020 03:44:26
	System	25 Aug 2020 03:44:26

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:52:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:44:25', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'd1f5ffe4-2814-42bb-88eb-627d3645912f' User entered '24 Aug 2020 23:44'	System	25 Aug 2020 03:44:26
	System	25 Aug 2020 03:44:26

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 5'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:52:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:32:02', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f823ac83-3449-421d-b5ef-1023c171cb29' User entered 'Yes (Y)'	System	26 Aug 2020 01:32:49
	System	26 Aug 2020 01:32:49

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:52:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:32:22', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f823ac83-3449-421d-b5ef-1023c171cb29' User entered '97.0'	System	26 Aug 2020 01:32:49
	System	26 Aug 2020 01:32:49

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:52:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:32:37', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f823ac83-3449-421d-b5ef-1023c171cb29'	System	26 Aug 2020 01:32:49
User entered 'No (N)'	System	26 Aug 2020 01:32:49

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:52:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:32:45', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f823ac83-3449-421d-b5ef-1023c171cb29' User entered '25 Aug 2020 21:32'	System	26 Aug 2020 01:32:49
	System	26 Aug 2020 01:32:49

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 6'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:52:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:28:26', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '528f9894-47d8-416a-986f-55e4bffbbfbc' User entered 'Yes (Y)'	System	26 Aug 2020 23:28:56
	System	26 Aug 2020 23:28:56

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:52:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:28:37', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '528f9894-47d8-416a-986f-55e4bffbbfbc' User entered '97.5'	System	26 Aug 2020 23:28:56
	System	26 Aug 2020 23:28:56

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:52:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:28:42', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '528f9894-47d8-416a-986f-55e4bffbbfbc'	System	26 Aug 2020 23:28:56
User entered 'No (N)'	System	26 Aug 2020 23:28:56

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:52:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:28:52', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '528f9894-47d8-416a-986f-55e4bffbbfbc' User entered '26 Aug 2020 19:28'	System	26 Aug 2020 23:28:56
	System	26 Aug 2020 23:28:56

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 7'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:52:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-28T08:25:49', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '37bdf4cb-25b5-416a-aac6-81702c309c6d' User entered 'Yes (Y)'	System	28 Aug 2020 12:26:09
	System	28 Aug 2020 12:26:09

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:52:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-28T08:25:58', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '37bdf4cb-25b5-416a-aac6-81702c309c6d' User entered '97.8'	System	28 Aug 2020 12:26:09
	System	28 Aug 2020 12:26:09

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:52:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-28T08:26:01', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '37bdf4cb-25b5-416a-aac6-81702c309c6d' User entered 'No (N)'	System	28 Aug 2020 12:26:09
	System	28 Aug 2020 12:26:09

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:52:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-28T08:26:05', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '37bdf4cb-25b5-416a-aac6-81702c309c6d' User entered '28 Aug 2020 08:26'	System	28 Aug 2020 12:26:09
	System	28 Aug 2020 12:26:09

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '21 Aug 2020 16:10'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '21 Aug 2020 18:40'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:57:09', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '30715b11-8066-4ee5-b3ef-2466e0bcecebe' User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 12:58:36
	System	22 Aug 2020 12:58:36

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:57:15', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '30715b11-8066-4ee5-b3ef-2466e0bcecb'	System	22 Aug 2020 12:58:36
User entered 'No (N)'	System	22 Aug 2020 12:58:36

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:58:08', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '30715b11-8066-4ee5-b3ef-2466e0bcecebe' User entered 'No (N)'	System	22 Aug 2020 12:58:36
	System	22 Aug 2020 12:58:36

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:58:20', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '30715b11-8066-4ee5-b3ef-2466e0bcecb'	System	22 Aug 2020 12:58:36
User entered 'None (1)'	System	22 Aug 2020 12:58:36

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:58:30', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '30715b11-8066-4ee5-b3ef-2466e0bcecb'	System	22 Aug 2020 12:58:36
User entered '22 Aug 2020 08:58'	System	22 Aug 2020 12:58:36

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '21 Aug 2020 19:35'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 2'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:01

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:28:18', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '54d4388c-f0a2-4776-ba5d-1335a6eb1152'	System	23 Aug 2020 13:29:37
User entered 'None (1)'	System	23 Aug 2020 13:29:37

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:28:39', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '54d4388c-f0a2-4776-ba5d-1335a6eb1152'	System	23 Aug 2020 13:29:37
User entered 'Yes (Y)'	System	23 Aug 2020 13:29:37

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:01

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:29:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '54d4388c-f0a2-4776-ba5d-1335a6eb1152' User entered '1'	System	23 Aug 2020 13:29:37
	System	23 Aug 2020 13:29:37

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:29:13', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '54d4388c-f0a2-4776-ba5d-1335a6eb1152'	System	23 Aug 2020 13:29:37
User entered 'Yes (Y)'	System	23 Aug 2020 13:29:37

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:01

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:29:19', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '54d4388c-f0a2-4776-ba5d-1335a6eb1152' User entered '1'	System	23 Aug 2020 13:29:37
	System	23 Aug 2020 13:29:37

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:01

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:29:26', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '54d4388c-f0a2-4776-ba5d-1335a6eb1152'	System	23 Aug 2020 13:29:37
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 13:29:37

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:29:35', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '54d4388c-f0a2-4776-ba5d-1335a6eb1152' User entered '23 Aug 2020 09:29'	System	23 Aug 2020 13:29:37
	System	23 Aug 2020 13:29:37

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 3'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:52:01

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:48:53', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'a0a6c86a-3085-4de2-8e07-0c042c55d2c2'	System	23 Aug 2020 20:49:42
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 20:49:42

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:52:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:49:10', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'a0a6c86a-3085-4de2-8e07-0c042c55d2c2'	System	23 Aug 2020 20:49:42
User entered 'No (N)'	System	23 Aug 2020 20:49:42

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:52:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:49:19', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'a0a6c86a-3085-4de2-8e07-0c042c55d2c2'	System	23 Aug 2020 20:49:42
User entered 'No (N)'	System	23 Aug 2020 20:49:42

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:52:01

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:49:35', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'a0a6c86a-3085-4de2-8e07-0c042c55d2c2'	System	23 Aug 2020 20:49:42
User entered 'None (1)'	System	23 Aug 2020 20:49:42

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:52:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:49:40', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'a0a6c86a-3085-4de2-8e07-0c042c55d2c2' User entered '23 Aug 2020 16:49'	System	23 Aug 2020 20:49:42
	System	23 Aug 2020 20:49:42

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 4'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:52:01

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:44:34', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f16e6665-eee1-4330-9486-40e7ae66e843'	System	25 Aug 2020 03:44:54
User entered 'None (1)'	System	25 Aug 2020 03:44:54

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:52:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:44:38', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f16e6665-eee1-4330-9486-40e7ae66e843'	System	25 Aug 2020 03:44:54
User entered 'No (N)'	System	25 Aug 2020 03:44:54

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:52:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:44:42', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f16e6665-eee1-4330-9486-40e7ae66e843'	System	25 Aug 2020 03:44:54
User entered 'No (N)'	System	25 Aug 2020 03:44:54

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:52:01

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:44:49', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f16e6665-eee1-4330-9486-40e7ae66e843'	System	25 Aug 2020 03:44:54
User entered 'None (1)'	System	25 Aug 2020 03:44:54

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:52:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:44:52', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f16e6665-eee1-4330-9486-40e7ae66e843'	System	25 Aug 2020 03:44:54
User entered '24 Aug 2020 23:44'	System	25 Aug 2020 03:44:54

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 5'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:52:01

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:33:16', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '36349a12-95b5-48a2-a3be-fc4ac1b69e3b' User entered 'None (1)'	System	26 Aug 2020 01:34:03
	System	26 Aug 2020 01:34:03

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:52:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:33:19', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '36349a12-95b5-48a2-a3be-fc4ac1b69e3b' User entered 'No (N)'	System	26 Aug 2020 01:34:03
	System	26 Aug 2020 01:34:03

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:52:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:33:26', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '36349a12-95b5-48a2-a3be-fc4ac1b69e3b' User entered 'No (N)'	System	26 Aug 2020 01:34:03
	System	26 Aug 2020 01:34:03

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:52:01

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:33:47', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '36349a12-95b5-48a2-a3be-fc4ac1b69e3b' User entered 'None (1)'	System	26 Aug 2020 01:34:03
	System	26 Aug 2020 01:34:03

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:52:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:33:58', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '36349a12-95b5-48a2-a3be-fc4ac1b69e3b' User entered '25 Aug 2020 21:33'	System	26 Aug 2020 01:34:03
	System	26 Aug 2020 01:34:03

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 6'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:52:01

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:28:57', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8533a060-5f62-4bc8-a5d5-8c22a5a54980' User entered 'None (1)'	System	26 Aug 2020 23:29:12
	System	26 Aug 2020 23:29:12

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:52:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:29:01', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8533a060-5f62-4bc8-a5d5-8c22a5a54980' User entered 'No (N)'	System	26 Aug 2020 23:29:12
	System	26 Aug 2020 23:29:12

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:52:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:29:03', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8533a060-5f62-4bc8-a5d5-8c22a5a54980' User entered 'No (N)'	System	26 Aug 2020 23:29:12
	System	26 Aug 2020 23:29:12

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:52:01

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:29:06', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8533a060-5f62-4bc8-a5d5-8c22a5a54980'	System	26 Aug 2020 23:29:12
User entered 'None (1)'	System	26 Aug 2020 23:29:12

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:52:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:29:10', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8533a060-5f62-4bc8-a5d5-8c22a5a54980' User entered '26 Aug 2020 19:29'	System	26 Aug 2020 23:29:12
	System	26 Aug 2020 23:29:12

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 7'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:52:01

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-28T08:25:22', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'b4d5b1bb-e853-42dd-8fa0-44b3d54eba20'	System	28 Aug 2020 12:25:46
User entered 'None (1)'	System	28 Aug 2020 12:25:46

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:52:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-28T08:25:28', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'b4d5b1bb-e853-42dd-8fa0-44b3d54eba20'	System	28 Aug 2020 12:25:46
User entered 'No (N)'	System	28 Aug 2020 12:25:46

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:52:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-28T08:25:32', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'b4d5b1bb-e853-42dd-8fa0-44b3d54eba20' User entered 'No (N)'	System	28 Aug 2020 12:25:46
	System	28 Aug 2020 12:25:46

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:52:01

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-28T08:25:39', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'b4d5b1bb-e853-42dd-8fa0-44b3d54eba20'	System	28 Aug 2020 12:25:46
User entered 'None (1)'	System	28 Aug 2020 12:25:46

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:52:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-28T08:25:42', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'b4d5b1bb-e853-42dd-8fa0-44b3d54eba20' User entered '28 Aug 2020 08:25'	System	28 Aug 2020 12:25:46
	System	28 Aug 2020 12:25:46

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '21 Aug 2020 16:10'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '21 Aug 2020 18:40'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:58:44', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '2d918e23-bb47-44ee-bd60-7e67d8b91cf8'	System	22 Aug 2020 12:59:38
User entered 'No interference with activity (1)'	System	22 Aug 2020 12:59:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:58:52', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '2d918e23-bb47-44ee-bd60-7e67d8b91cf8'	System	22 Aug 2020 12:59:38
User entered 'Some interference with activity (2)'	System	22 Aug 2020 12:59:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:59:11', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '2d918e23-bb47-44ee-bd60-7e67d8b91cf8'	System	22 Aug 2020 12:59:38
User entered 'Some interference with activity (2)'	System	22 Aug 2020 12:59:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:59:15', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '2d918e23-bb47-44ee-bd60-7e67d8b91cf8'	System	22 Aug 2020 12:59:38
User entered 'Some interference with activity (2)'	System	22 Aug 2020 12:59:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:59:22', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '2d918e23-bb47-44ee-bd60-7e67d8b91cf8' User entered 'None (0)'	System	22 Aug 2020 12:59:38
	System	22 Aug 2020 12:59:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:59:25', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '2d918e23-bb47-44ee-bd60-7e67d8b91cf8' User entered 'None (0)'	System	22 Aug 2020 12:59:38
	System	22 Aug 2020 12:59:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:59:29', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '2d918e23-bb47-44ee-bd60-7e67d8b91cf8'	System	22 Aug 2020 12:59:38
User entered 'No (N)'	System	22 Aug 2020 12:59:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:59:36', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '2d918e23-bb47-44ee-bd60-7e67d8b91cf8' User entered '22 Aug 2020 08:59'	System	22 Aug 2020 12:59:38
	System	22 Aug 2020 12:59:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '21 Aug 2020 19:35'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 2'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:29:49', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8b35d93d-4e11-4c77-b349-fe1d98567f7e' User entered 'No interference with activity (1)'	System	23 Aug 2020 13:30:27
	System	23 Aug 2020 13:30:27

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:29:56', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8b35d93d-4e11-4c77-b349-fe1d98567f7e' User entered 'Some interference with activity (2)'	System	23 Aug 2020 13:30:27
	System	23 Aug 2020 13:30:27

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:30:04', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8b35d93d-4e11-4c77-b349-fe1d98567f7e'	System	23 Aug 2020 13:30:27
User entered 'Some interference with activity (2)'	System	23 Aug 2020 13:30:27

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:30:08', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8b35d93d-4e11-4c77-b349-fe1d98567f7e' User entered 'Some interference with activity (2)'	System	23 Aug 2020 13:30:27
	System	23 Aug 2020 13:30:27

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:30:12', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8b35d93d-4e11-4c77-b349-fe1d98567f7e' User entered 'None (0)'	System	23 Aug 2020 13:30:27
	System	23 Aug 2020 13:30:27

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:30:15', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8b35d93d-4e11-4c77-b349-fe1d98567f7e' User entered 'None (0)'	System	23 Aug 2020 13:30:27
	System	23 Aug 2020 13:30:27

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:01

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:30:20', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8b35d93d-4e11-4c77-b349-fe1d98567f7e' User entered 'No (N)'	System	23 Aug 2020 13:30:27
	System	23 Aug 2020 13:30:27

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:30:26', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8b35d93d-4e11-4c77-b349-fe1d98567f7e' User entered '23 Aug 2020 09:30'	System	23 Aug 2020 13:30:27
	System	23 Aug 2020 13:30:27

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 3'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:49:46', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '95ca0d50-78bc-4ffd-be13-e23e0b7f4c70' User entered 'None (0)'	System	23 Aug 2020 20:50:22
	System	23 Aug 2020 20:50:22

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:49:52', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '95ca0d50-78bc-4ffd-be13-e23e0b7f4c70' User entered 'None (0)'	System	23 Aug 2020 20:50:22
	System	23 Aug 2020 20:50:22

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:49:58', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '95ca0d50-78bc-4ffd-be13-e23e0b7f4c70'	System	23 Aug 2020 20:50:22
User entered 'No interference with activity (1)'	System	23 Aug 2020 20:50:22

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:50:03', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '95ca0d50-78bc-4ffd-be13-e23e0b7f4c70'	System	23 Aug 2020 20:50:22
User entered 'No interference with activity (1)'	System	23 Aug 2020 20:50:22

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:50:06', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '95ca0d50-78bc-4ffd-be13-e23e0b7f4c70' User entered 'None (0)'	System	23 Aug 2020 20:50:22
	System	23 Aug 2020 20:50:22

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:50:09', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '95ca0d50-78bc-4ffd-be13-e23e0b7f4c70'	System	23 Aug 2020 20:50:22
User entered 'None (0)'	System	23 Aug 2020 20:50:22

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:01

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:50:14', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '95ca0d50-78bc-4ffd-be13-e23e0b7f4c70' User entered 'No (N)'	System	23 Aug 2020 20:50:22
	System	23 Aug 2020 20:50:22

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:50:19', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '95ca0d50-78bc-4ffd-be13-e23e0b7f4c70' User entered '23 Aug 2020 16:50'	System	23 Aug 2020 20:50:22
	System	23 Aug 2020 20:50:22

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 4'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:44:58', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '597a8a3e-b9aa-41e6-9583-8d4ca6dad6bf' User entered 'None (0)'	System	25 Aug 2020 03:45:25
	System	25 Aug 2020 03:45:25

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:45:01', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '597a8a3e-b9aa-41e6-9583-8d4ca6dad6bf' User entered 'None (0)'	System	25 Aug 2020 03:45:25
	System	25 Aug 2020 03:45:25

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:45:06', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '597a8a3e-b9aa-41e6-9583-8d4ca6dad6bf' User entered 'No interference with activity (1)'	System	25 Aug 2020 03:45:25
	System	25 Aug 2020 03:45:25

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:45:09', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '597a8a3e-b9aa-41e6-9583-8d4ca6dad6bf' User entered 'No interference with activity (1)'	System	25 Aug 2020 03:45:25
	System	25 Aug 2020 03:45:25

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:45:13', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '597a8a3e-b9aa-41e6-9583-8d4ca6dad6bf' User entered 'None (0)'	System	25 Aug 2020 03:45:25
	System	25 Aug 2020 03:45:25

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:45:16', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '597a8a3e-b9aa-41e6-9583-8d4ca6dad6bf' User entered 'None (0)'	System	25 Aug 2020 03:45:25
	System	25 Aug 2020 03:45:25

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:01

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:45:20', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '597a8a3e-b9aa-41e6-9583-8d4ca6dad6bf' User entered 'No (N)'	System	25 Aug 2020 03:45:25
	System	25 Aug 2020 03:45:25

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:45:24', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '597a8a3e-b9aa-41e6-9583-8d4ca6dad6bf' User entered '24 Aug 2020 23:45'	System	25 Aug 2020 03:45:25
	System	25 Aug 2020 03:45:25

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 5'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:34:08', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f1c13421-f1d3-48aa-a6e5-73aa4d383040' User entered 'None (0)'	System	26 Aug 2020 01:34:36
	System	26 Aug 2020 01:34:36

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:34:12', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f1c13421-f1d3-48aa-a6e5-73aa4d383040' User entered 'None (0)'	System	26 Aug 2020 01:34:36
	System	26 Aug 2020 01:34:36

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:34:15', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f1c13421-f1d3-48aa-a6e5-73aa4d383040'	System	26 Aug 2020 01:34:36
User entered 'None (0)'	System	26 Aug 2020 01:34:36

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:34:19', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f1c13421-f1d3-48aa-a6e5-73aa4d383040' User entered 'None (0)'	System	26 Aug 2020 01:34:36
	System	26 Aug 2020 01:34:36

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:34:22', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f1c13421-f1d3-48aa-a6e5-73aa4d383040' User entered 'None (0)'	System	26 Aug 2020 01:34:36
	System	26 Aug 2020 01:34:36

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:34:25', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f1c13421-f1d3-48aa-a6e5-73aa4d383040'	System	26 Aug 2020 01:34:36
User entered 'None (0)'	System	26 Aug 2020 01:34:36

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:01

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:34:29', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f1c13421-f1d3-48aa-a6e5-73aa4d383040' User entered 'No (N)'	System	26 Aug 2020 01:34:36
	System	26 Aug 2020 01:34:36

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:34:33', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f1c13421-f1d3-48aa-a6e5-73aa4d383040' User entered '25 Aug 2020 21:34'	System	26 Aug 2020 01:34:36
	System	26 Aug 2020 01:34:36

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 6'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:29:15', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '0944b17c-fc4c-491c-b8e1-ae5442afd619' User entered 'None (0)'	System	26 Aug 2020 23:29:38
	System	26 Aug 2020 23:29:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:29:17', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '0944b17c-fc4c-491c-b8e1-ae5442afd619' User entered 'None (0)'	System	26 Aug 2020 23:29:38
	System	26 Aug 2020 23:29:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:29:19', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '0944b17c-fc4c-491c-b8e1-ae5442afd619' User entered 'None (0)'	System	26 Aug 2020 23:29:38
	System	26 Aug 2020 23:29:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:29:22', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '0944b17c-fc4c-491c-b8e1-ae5442afd619' User entered 'None (0)'	System	26 Aug 2020 23:29:38
	System	26 Aug 2020 23:29:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:29:25', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '0944b17c-fc4c-491c-b8e1-ae5442afd619' User entered 'None (0)'	System	26 Aug 2020 23:29:38
	System	26 Aug 2020 23:29:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:29:28', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '0944b17c-fc4c-491c-b8e1-ae5442afd619' User entered 'None (0)'	System	26 Aug 2020 23:29:38
	System	26 Aug 2020 23:29:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:01

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:29:31', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '0944b17c-fc4c-491c-b8e1-ae5442afd619'	System	26 Aug 2020 23:29:38
User entered 'No (N)'	System	26 Aug 2020 23:29:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:29:34', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '0944b17c-fc4c-491c-b8e1-ae5442afd619' User entered '26 Aug 2020 19:29'	System	26 Aug 2020 23:29:38
	System	26 Aug 2020 23:29:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 7'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-28T08:26:09', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '41a8497b-2b7b-433b-b48e-a3e1d3d1d8e2'	System	28 Aug 2020 12:26:30
User entered 'None (0)'	System	28 Aug 2020 12:26:30

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-28T08:26:12', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '41a8497b-2b7b-433b-b48e-a3e1d3d1d8e2' User entered 'None (0)'	System	28 Aug 2020 12:26:30
	System	28 Aug 2020 12:26:30

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-28T08:26:14', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '41a8497b-2b7b-433b-b48e-a3e1d3d1d8e2'	System	28 Aug 2020 12:26:30
User entered 'None (0)'	System	28 Aug 2020 12:26:30

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-28T08:26:16', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '41a8497b-2b7b-433b-b48e-a3e1d3d1d8e2' User entered 'None (0)'	System	28 Aug 2020 12:26:30
	System	28 Aug 2020 12:26:30

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-28T08:26:18', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '41a8497b-2b7b-433b-b48e-a3e1d3d1d8e2' User entered 'None (0)'	System	28 Aug 2020 12:26:30
	System	28 Aug 2020 12:26:30

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-28T08:26:20', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '41a8497b-2b7b-433b-b48e-a3e1d3d1d8e2' User entered 'None (0)'	System	28 Aug 2020 12:26:30
	System	28 Aug 2020 12:26:30

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:01

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-28T08:26:25', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '41a8497b-2b7b-433b-b48e-a3e1d3d1d8e2'	System	28 Aug 2020 12:26:30
User entered 'No (N)'	System	28 Aug 2020 12:26:30

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-28T08:26:28', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '41a8497b-2b7b-433b-b48e-a3e1d3d1d8e2' User entered '28 Aug 2020 08:26'	System	28 Aug 2020 12:26:30
	System	28 Aug 2020 12:26:30

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 19:54:01

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:52:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 14:32:47

US3522297

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 14:32:47

US3522297

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 14:32:47

US3522297

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'NO ONGOING OR NEW AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE OR PREGNANCY RISK. Patient took aspirin for joint pain' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Aug 2020 14:33:28
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk'	(b) (4), (b) (6)	28 Aug 2020 14:32:47

US3522297

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 14:32:51

US3522297

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered '1'	System	28 Aug 2020 14:32:51

US3522297

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	04 Sep 2020 17:42:41

US3522297

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered '04 Sep 2020' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	10 Nov 2020 17:54:00
User entered '4 Sep 2020'	Tyler Prentiss (b) (4) (b) (4)	04 Sep 2020 17:42:41

US3522297

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Contact Made (CONTACT MADE)'	Tyler Prentiss (b) (4)	04 Sep 2020 17:42:41

US3522297

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure.'	(b) (4) Tyler Prentiss (b) (4)	04 Sep 2020 17:42:41

US3522297

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)'	(b) (4) Tyler Prentiss (b) (4)	04 Sep 2020 17:44:03

US3522297

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered '1'	System	04 Sep 2020 17:44:03

US3522297

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:59:50

US3522297

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:59:50

US3522297

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:59:50

US3522297

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
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: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:00:15
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk. patient reports stiffness but states that he believes it is more related to aging than the injection' (non-conformant).	(b) (4), (b) (6)	11 Sep 2020 14:59:50

US3522297

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:01:01

US3522297

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered '1'	System	16 Sep 2020 18:01:01

US3522297

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User closed query 'Per CDM : Please provide the data for the Vital signs-Dosing form.' (Site from DM).	(b) (4)	
Query 'Per CDM : Please provide the data for the Vital signs-Dosing form.' answered with 'updated no on dosing form' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 08:19:41
Query 'Per CDM : Please provide the data for the Vital signs-Dosing form.' answered with 'updated no on dosing form' (Site from DM).	Sharon Mathys (b) (4)	06 Nov 2020 17:27:50
User opened query 'Per CDM : Please provide the data for the Vital signs-Dosing form.' (Site from DM).	(b) (4)	
User opened query 'Per CDM : Please provide the data for the Vital signs-Dosing form.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:55:14
User entered 'No (N)'	Sharon Mathys (b) (4)	05 Oct 2020 19:59:02
	(b) (4)	

US3522297

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 19:59:02

US3522297

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered empty.	(b) (4) Sharon Mathys (b) (4)	05 Oct 2020 19:59:02

US3522297

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered 'VISIT2'	System	05 Oct 2020 19:59:02

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User accepted default value 'Pre-Dose (PREDOSE)'	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User accepted default value 'Post-Dose (POSTDOSE)'	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:24

US3522297

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:24

US3522297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User closed query 'Per CDM: Please complete all forms for visit 2 day 29. Please consider entering No if not performed.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 08:19:31
Query 'Per CDM: Please complete all forms for visit 2 day 29. Please consider entering No if not performed.' answered with 'updated no on all forms as necessary' (Site from DM).	Sharon Mathys (b) (4)	06 Nov 2020 17:28:01
User opened query 'Per CDM: Please complete all forms for visit 2 day 29. Please consider entering No if not performed.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:46:01
User entered 'No (N)'	Sharon Mathys (b) (4)	09 Oct 2020 18:52:57

US3522297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'Confirmed COVID-19 (COVID)'	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 18:52:57

US3522297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 18:52:57

US3522297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	09 Oct 2020 18:52:57

US3522297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 18:52:57

US3522297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 18:52:57

US3522297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	09 Oct 2020 18:52:57

US3522297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 18:52:57

US3522297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	09 Oct 2020 18:52:57

US3522297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	09 Oct 2020 18:52:57

US3522297

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:29

US3522297

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:29

US3522297

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:29

US3522297

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 17:27:29

US3522297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:52:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:35

US3522297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:52:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:35

US3522297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:52:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:35

US3522297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:52:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered empty.	(b) (4) Sharon Mathys (b) (4)	06 Nov 2020 17:27:35

US3522297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:52:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 17:27:35

US3522297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:52:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 17:27:35

US3522297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:52:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4)	06 Nov 2020 17:27:35

US3522297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:52:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered empty.	(b) (4) Sharon Mathys (b) (4)	06 Nov 2020 17:27:35

US3522297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:52:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 17:27:35

US3522297

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 19:59:07

US3522297

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered '1'	System	05 Oct 2020 19:59:07

US3522297

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 19:09:51
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 18:53:41

US3522297

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered '25 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 19:09:51
User entered empty.	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 18:53:41

US3522297

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 19:09:51
User entered empty.	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 18:53:41

US3522297

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Taken over by daily telemedicine illness visits.'	Sharon Mathys (b) (4)	09 Oct 2020 18:53:41

US3522297

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 18:53:48

US3522297

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered '1'	System	09 Oct 2020 18:53:48

US3522297

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 19:10:06
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 18:54:14

US3522297

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered '02 Oct 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 19:10:06
User entered empty.	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 18:54:14

US3522297

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 19:10:06
User entered empty.	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 18:54:14

US3522297

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'TAKEN OVER BY DAILY TELEMEDICINE ILLNESS VISITS with Study physician'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 18:54:14

US3522297

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 18:56:46

US3522297

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered '1'	System	09 Oct 2020 18:56:46

US3522297

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)'	(b) (4) Kristin Eis (b) (4) (b) (4)	09 Oct 2020 18:57:55

US3522297

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered empty.	(b) (4) Kristin Eis (b) (4)	09 Oct 2020 18:57:55

US3522297

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered empty.	(b) (4) Kristin Eis (b) (4)	09 Oct 2020 18:57:55

US3522297

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'Patient was confirmed COVID-19 positive, has been having telemedicine visits with the study doctor since.'	Kristin Eis (b) (4)	09 Oct 2020 18:57:55

US3522297

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 19:10:18

US3522297

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered '1'	System	09 Oct 2020 19:10:18

US3522297

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User closed query 'Per CDM: Please complete all forms for Visit 3 Day 57. Please consider entering NO if not performed.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 01:49:39
Query 'Per CDM: Please complete all forms for Visit 3 Day 57. Please consider entering NO if not performed.' answered with 'missed because illness visit' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 21:03:10
User opened query 'Per CDM: Please complete all forms for Visit 3 Day 57. Please consider entering NO if not performed.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:47:06
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:20:25

US3522297

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:20:25

US3522297

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered empty.	(b) (4) Sharon Mathys (b) (4)	19 Oct 2020 14:20:25

US3522297

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered 'VISIT3'	System	19 Oct 2020 14:20:25

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered empty.	(b) (4) Sharon Mathys (b) (4)	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44

US3522297

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 18:55:43

US3522297

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 18:55:43

US3522297

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4)	06 Nov 2020 18:55:53

US3522297

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered empty.	(b) (4) Sharon Mathys (b) (4)	06 Nov 2020 18:55:53

US3522297

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:41:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 18:55:53

US3522297

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered empty.	System	06 Nov 2020 18:55:53

US3522297

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:41:18
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:20:31

US3522297

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered '1'	System	19 Oct 2020 14:20:31

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 64'	System	21 Aug 2020 19:54:01

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-10-21T18:54:33', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '0bb21a2b-2565-4221-9e36-e4b702ab6818'	System	21 Oct 2020 22:54:53
User entered 'No (N)'	System	21 Oct 2020 22:54:53

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-10-21T18:54:28', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '0bb21a2b-2565-4221-9e36-e4b702ab6818'	System	21 Oct 2020 22:54:53
User entered 'No (N)'	System	21 Oct 2020 22:54:53

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-10-21T18:54:49', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '0bb21a2b-2565-4221-9e36-e4b702ab6818' User entered '21 Oct 2020 18:54:49'	System	21 Oct 2020 22:54:53
	System	21 Oct 2020 22:54:53

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 19:54:01

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 71'	System	21 Aug 2020 19:54:01

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-10-30T12:31:04', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f09bb04d-881a-4798-9ecf-54a6bdf28b7c'	System	30 Oct 2020 16:32:14
User entered 'No (N)'	System	30 Oct 2020 16:32:14

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-10-30T12:31:30', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f09bb04d-881a-4798-9ecf-54a6bdf28b7c'	System	30 Oct 2020 16:32:14
User entered 'No (N)'	System	30 Oct 2020 16:32:14

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-10-30T12:32:08', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f09bb04d-881a-4798-9ecf-54a6bdf28b7c' User entered '30 Oct 2020 12:32:08'	System	30 Oct 2020 16:32:14
	System	30 Oct 2020 16:32:14

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 19:54:01

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 78'	System	21 Aug 2020 19:54:01

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-11-04T06:46:38', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8eb738f8-8924-499f-b69d-334500aaef2d' User entered 'No (N)'	System	04 Nov 2020 11:50:32
	System	04 Nov 2020 11:50:32

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-11-04T06:46:48', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8eb738f8-8924-499f-b69d-334500aaef2d' User entered 'No (N)'	System	04 Nov 2020 11:50:32
	System	04 Nov 2020 11:50:32

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-11-04T06:50:29', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8eb738f8-8924-499f-b69d-334500aaef2d' User entered '04 Nov 2020 06:50:29'	System	04 Nov 2020 11:50:32
	System	04 Nov 2020 11:50:32

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 19:54:01

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:12:03
Data entry locked.	System	21 Aug 2020 19:54:01
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02
Data entry locked.	System	21 Aug 2020 19:54:01
User entered 'Day 92'	System	21 Aug 2020 19:54:01

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[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)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with 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)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02
Data entry locked.	System	21 Aug 2020 19:54:01
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 19:54:01

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:54:02
Data entry locked.	System	21 Aug 2020 19:54:01
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 19:54:01

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-11-22T08:18:16', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'e5e49dea-9559-4113-945a-863eb57c50c2'	System	22 Nov 2020 13:19:06
User entered 'No (N)'	System	22 Nov 2020 13:19:06

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-11-22T08:18:23', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'e5e49dea-9559-4113-945a-863eb57c50c2'	System	22 Nov 2020 13:19:06
User entered 'Yes (Y)'	System	22 Nov 2020 13:19:06

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-11-22T08:18:37', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'e5e49dea-9559-4113-945a-863eb57c50c2'	System	22 Nov 2020 13:19:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Nov 2020 13:19:06

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-11-22T08:18:58', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'e5e49dea-9559-4113-945a-863eb57c50c2' User entered '22 Nov 2020 08:18:58'	System	22 Nov 2020 13:19:06
	System	22 Nov 2020 13:19:06

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-12-01T12:02:07', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '1b8d5f59-3da2-4dfa-805f-6284a28a739e'	System	01 Dec 2020 17:02:33
User entered 'No (N)'	System	01 Dec 2020 17:02:33

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-12-01T12:02:20', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '1b8d5f59-3da2-4dfa-805f-6284a28a739e'	System	01 Dec 2020 17:02:33
User entered 'No (N)'	System	01 Dec 2020 17:02:33

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-12-01T12:02:30', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '1b8d5f59-3da2-4dfa-805f-6284a28a739e'	System	01 Dec 2020 17:02:33
User entered '01 Dec 2020 12:02:30'	System	01 Dec 2020 17:02:33

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-12-07T19:26:25', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '33462bab-f231-4d7e-9b4c-b82c2eb43dca' User entered 'No (N)'	System	08 Dec 2020 00:26:48
	System	08 Dec 2020 00:26:48

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-12-07T19:26:32', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '33462bab-f231-4d7e-9b4c-b82c2eb43dca' User entered 'No (N)'	System	08 Dec 2020 00:26:48
	System	08 Dec 2020 00:26:48

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-12-07T19:26:44', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '33462bab-f231-4d7e-9b4c-b82c2eb43dca' User entered '07 Dec 2020 19:26:44'	System	08 Dec 2020 00:26:48
	System	08 Dec 2020 00:26:48

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-12-13T09:13:15', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '285145e4-3194-4a99-8388-6f60e7b5bbd8'	System	13 Dec 2020 14:13:30
User entered 'No (N)'	System	13 Dec 2020 14:13:30

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-12-13T09:13:22', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '285145e4-3194-4a99-8388-6f60e7b5bbd8'	System	13 Dec 2020 14:13:30
User entered 'No (N)'	System	13 Dec 2020 14:13:30

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-12-13T09:13:28', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '285145e4-3194-4a99-8388-6f60e7b5bbd8'	System	13 Dec 2020 14:13:30
User entered '13 Dec 2020 09:13:28'	System	13 Dec 2020 14:13:30

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-12-20T10:03:51', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'cfb83c3e-3971-4e6d-971e-d57178c81726' User entered 'No (N)'	System	20 Dec 2020 15:04:17
	System	20 Dec 2020 15:04:17

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-12-20T10:04:04', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'cfb83c3e-3971-4e6d-971e-d57178c81726' User entered 'No (N)'	System	20 Dec 2020 15:04:17
	System	20 Dec 2020 15:04:17

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-12-20T10:04:12', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'cfb83c3e-3971-4e6d-971e-d57178c81726' User entered '20 Dec 2020 10:04:12'	System	20 Dec 2020 15:04:17
	System	20 Dec 2020 15:04:17

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-12-29T12:01:20', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'b061a9e1-91ff-4021-be6a-edc821373c29'	System	29 Dec 2020 19:01:45
User entered 'No (N)'	System	29 Dec 2020 19:01:45

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-12-29T12:01:26', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'b061a9e1-91ff-4021-be6a-edc821373c29'	System	29 Dec 2020 19:01:45
User entered 'No (N)'	System	29 Dec 2020 19:01:45

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-12-29T12:01:33', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'b061a9e1-91ff-4021-be6a-edc821373c29' User entered '29 Dec 2020 12:01:33'	System	29 Dec 2020 19:01:45
	System	29 Dec 2020 19:01:45

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-01-05T12:31:15', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '77d47b54-85f2-483f-b9a6-a26bc503d13b'	System	05 Jan 2021 17:31:29
User entered 'No (N)'	System	05 Jan 2021 17:31:29

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-01-05T12:31:20', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '77d47b54-85f2-483f-b9a6-a26bc503d13b' User entered 'No (N)'	System	05 Jan 2021 17:31:29

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-01-05T12:31:26', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '77d47b54-85f2-483f-b9a6-a26bc503d13b' User entered '05 Jan 2021 12:31:26'	System	05 Jan 2021 17:31:29
	System	05 Jan 2021 17:31:29

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-01-10T12:59:34', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '84ec9c51-6960-4c6c-a8af-efe22e816ef5' User entered 'No (N)'	System	10 Jan 2021 18:00:02
	System	10 Jan 2021 18:00:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-01-10T12:59:48', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '84ec9c51-6960-4c6c-a8af-efe22e816ef5' User entered 'No (N)'	System	10 Jan 2021 18:00:02
	System	10 Jan 2021 18:00:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-01-10T12:59:56', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '84ec9c51-6960-4c6c-a8af-efe22e816ef5' User entered '10 Jan 2021 12:59:56'	System	10 Jan 2021 18:00:02
	System	10 Jan 2021 18:00:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-01-18T08:50:04', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '6a87407a-af19-49a7-b8d7-33c083837317'	System	18 Jan 2021 13:50:21
User entered 'No (N)'	System	18 Jan 2021 13:50:21

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-01-18T08:50:11', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '6a87407a-af19-49a7-b8d7-33c083837317'	System	18 Jan 2021 13:50:21
User entered 'No (N)'	System	18 Jan 2021 13:50:21

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-01-18T08:50:18', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '6a87407a-af19-49a7-b8d7-33c083837317' User entered '18 Jan 2021 08:50:18'	System	18 Jan 2021 13:50:21
	System	18 Jan 2021 13:50:21

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-01-26T10:08:11', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '889e8f3d-0c44-4a7a-93fb-548393055d24'	System	26 Jan 2021 15:09:38
User entered 'No (N)'	System	26 Jan 2021 15:09:38

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-01-26T10:08:17', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '889e8f3d-0c44-4a7a-93fb-548393055d24'	System	26 Jan 2021 15:09:38
User entered 'No (N)'	System	26 Jan 2021 15:09:38

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-01-26T10:08:23', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '889e8f3d-0c44-4a7a-93fb-548393055d24' User entered '26 Jan 2021 10:08:23'	System	26 Jan 2021 15:09:38
	System	26 Jan 2021 15:09:38

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-01-31T10:51:43', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'a7d3b748-7272-4686-b134-bbebb8824938'	System	31 Jan 2021 15:52:01
User entered 'No (N)'	System	31 Jan 2021 15:52:01

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-01-31T10:51:54', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'a7d3b748-7272-4686-b134-bbebb8824938' User entered 'No (N)'	System	31 Jan 2021 15:52:01
	System	31 Jan 2021 15:52:01

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-01-31T10:51:58', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'a7d3b748-7272-4686-b134-bbebb8824938' User entered '31 Jan 2021 10:51:58'	System	31 Jan 2021 15:52:01
	System	31 Jan 2021 15:52:01

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-02-07T00:02:57', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '1e845829-5883-405e-9b8b-e44cc65f153f'	System	07 Feb 2021 05:03:27
User entered 'No (N)'	System	07 Feb 2021 05:03:27

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-02-07T00:02:59', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '1e845829-5883-405e-9b8b-e44cc65f153f'	System	07 Feb 2021 05:03:27
User entered 'No (N)'	System	07 Feb 2021 05:03:27

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2021-02-07T00:03:03', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '1e845829-5883-405e-9b8b-e44cc65f153f' User entered '07 Feb 2021 00:03:03'	System	07 Feb 2021 05:03:27
	System	07 Feb 2021 05:03:27

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-02-23T12:03:33', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '721c3335-ee64-4bf6-8bc7-bae824e52625'	System	23 Feb 2021 17:15:57
User entered 'No (N)'	System	23 Feb 2021 17:15:57

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-02-23T12:02:55', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '721c3335-ee64-4bf6-8bc7-bae824e52625'	System	23 Feb 2021 17:15:57
User entered 'No (N)'	System	23 Feb 2021 17:15:57

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-02-23T12:03:41', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '721c3335-ee64-4bf6-8bc7-bae824e52625' User entered '23 Feb 2021 12:03:41'	System	23 Feb 2021 17:15:57
	System	23 Feb 2021 17:15:57

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-03-01T09:44:18-05:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '13c9e329-1aea-4e7e-b89c-d70e2dd50c18'	System	01 Mar 2021 14:44:58
User entered 'No (N)'	System	01 Mar 2021 14:44:58

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-03-01T09:44:20-05:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '13c9e329-1aea-4e7e-b89c-d70e2dd50c18'	System	01 Mar 2021 14:44:58
User entered 'No (N)'	System	01 Mar 2021 14:44:58

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-03-01T09:44:25-05:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '13c9e329-1aea-4e7e-b89c-d70e2dd50c18' User entered '01 Mar 2021 09:44:25'	System	01 Mar 2021 14:44:58
	System	01 Mar 2021 14:44:58

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-03-08T17:26:37-05:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'ff1effb2-4e1f-4fd3-9a04-fe814c7c71e1'	System	08 Mar 2021 22:26:46
User entered 'No (N)'	System	08 Mar 2021 22:26:46

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-03-08T17:26:39-05:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'ff1effb2-4e1f-4fd3-9a04-fe814c7c71e1'	System	08 Mar 2021 22:26:46
User entered 'No (N)'	System	08 Mar 2021 22:26:46

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-03-08T17:26:43-05:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'ff1effb2-4e1f-4fd3-9a04-fe814c7c71e1' User entered '08 Mar 2021 17:26:43'	System	08 Mar 2021 22:26:46
	System	08 Mar 2021 22:26:46

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-03-16T12:45:53-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '93ca20e6-2899-430b-bc8a-b157afef1b73'	System	16 Mar 2021 16:46:31
User entered 'No (N)'	System	16 Mar 2021 16:46:31

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-03-16T12:45:58-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '93ca20e6-2899-430b-bc8a-b157afef1b73'	System	16 Mar 2021 16:46:31
User entered 'No (N)'	System	16 Mar 2021 16:46:31

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-03-16T12:46:28-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '93ca20e6-2899-430b-bc8a-b157afef1b73' User entered '16 Mar 2021 12:46:28'	System	16 Mar 2021 16:46:31
	System	16 Mar 2021 16:46:31

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-03-21T00:20:51-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '2797bf7e-dc97-40ed-8db6-91174eabbfa6'	System	21 Mar 2021 04:21:02
User entered 'No (N)'	System	21 Mar 2021 04:21:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-03-21T00:20:53-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '2797bf7e-dc97-40ed-8db6-91174eabbfa6'	System	21 Mar 2021 04:21:02
User entered 'No (N)'	System	21 Mar 2021 04:21:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-03-21T00:20:58-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '2797bf7e-dc97-40ed-8db6-91174eabbfa6'	System	21 Mar 2021 04:21:02
User entered '21 Mar 2021 00:20:58'	System	21 Mar 2021 04:21:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-03-28T08:01:12-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8888d992-ba86-4e21-8033-3624ec5d8fd1'	System	28 Mar 2021 12:01:43
User entered 'No (N)'	System	28 Mar 2021 12:01:43

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-03-28T08:01:26-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8888d992-ba86-4e21-8033-3624ec5d8fd1'	System	28 Mar 2021 12:01:43
User entered 'No (N)'	System	28 Mar 2021 12:01:43

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-03-28T08:01:39-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8888d992-ba86-4e21-8033-3624ec5d8fd1' User entered '28 Mar 2021 08:01:39'	System	28 Mar 2021 12:01:43
	System	28 Mar 2021 12:01:43

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-04-06T12:01:53-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '44f0e367-f193-413a-a02c-fe1be56db65c'	System	06 Apr 2021 16:06:53
User entered 'No (N)'	System	06 Apr 2021 16:06:53

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-04-06T12:01:56-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '44f0e367-f193-413a-a02c-fe1be56db65c'	System	06 Apr 2021 16:06:53
User entered 'No (N)'	System	06 Apr 2021 16:06:53

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-04-06T12:02:01-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '44f0e367-f193-413a-a02c-fe1be56db65c'	System	06 Apr 2021 16:06:53
User entered '06 Apr 2021 12:02:01'	System	06 Apr 2021 16:06:53

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-04-11T01:11:45-05:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '2f847f26-b007-4efa-8291-22d968b01fc4'	System	11 Apr 2021 06:11:57
User entered 'No (N)'	System	11 Apr 2021 06:11:57

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-04-11T01:11:51-05:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '2f847f26-b007-4efa-8291-22d968b01fc4'	System	11 Apr 2021 06:11:57
User entered 'No (N)'	System	11 Apr 2021 06:11:57

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-04-11T01:11:55-05:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '2f847f26-b007-4efa-8291-22d968b01fc4'	System	11 Apr 2021 06:11:57
User entered '11 Apr 2021 01:11:55'	System	11 Apr 2021 06:11:57

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-04-20T12:40:52-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '13aa7ce7-794e-4a62-890e-21e609bf6515'	System	20 Apr 2021 16:41:02
User entered 'No (N)'	System	20 Apr 2021 16:41:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-04-20T12:40:54-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '13aa7ce7-794e-4a62-890e-21e609bf6515'	System	20 Apr 2021 16:41:02
User entered 'No (N)'	System	20 Apr 2021 16:41:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-04-20T12:40:59-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '13aa7ce7-794e-4a62-890e-21e609bf6515'	System	20 Apr 2021 16:41:02
User entered '20 Apr 2021 12:40:59'	System	20 Apr 2021 16:41:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-04-26T07:39:34-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '9560c602-ff18-439b-889f-fe18e447ee85'	System	26 Apr 2021 11:39:42
User entered 'No (N)'	System	26 Apr 2021 11:39:42

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-04-26T07:39:37-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '9560c602-ff18-439b-889f-fe18e447ee85'	System	26 Apr 2021 11:39:42
User entered 'No (N)'	System	26 Apr 2021 11:39:42

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-04-26T07:39:40-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '9560c602-ff18-439b-889f-fe18e447ee85'	System	26 Apr 2021 11:39:42
User entered '26 Apr 2021 07:39:40'	System	26 Apr 2021 11:39:42

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-05-02T00:09:46-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '7d5cc5eb-d6da-449e-ade2-8e210fef5345'	System	02 May 2021 04:09:54
User entered 'No (N)'	System	02 May 2021 04:09:54

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-05-02T00:09:48-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '7d5cc5eb-d6da-449e-ade2-8e210fef5345'	System	02 May 2021 04:09:54
User entered 'No (N)'	System	02 May 2021 04:09:54

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-05-02T00:09:52-04:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '7d5cc5eb-d6da-449e-ade2-8e210fef5345'	System	02 May 2021 04:09:54
User entered '02 May 2021 00:09:52'	System	02 May 2021 04:09:54

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:52:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:54:02

US3522297

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:52:01

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-03-02T10:23:37-05:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '635763be-2396-4bc2-9e80-a836e2d5c1cd' User entered 'No (N)'	System	02 Mar 2021 15:23:52
	System	02 Mar 2021 15:23:52

US3522297

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:52:01

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:21:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18080C45-9943-4CC6-AD36-AF7550A75D48)', Time: '2021-03-02T10:23:49-05:00', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '635763be-2396-4bc2-9e80-a836e2d5c1cd' User entered '02 Mar 2021 10:23:49'	System	02 Mar 2021 15:23:52
	System	02 Mar 2021 15:23:52

US3522297

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 15:16:46

US3522297

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 15:16:46

US3522297

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 15:16:46

US3522297

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications. Mother in law came down with COVID 19 on 29 OCT 2020. Has been taking care of her since 6nov'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 15:16:46

US3522297

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 15:16:06

US3522297

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:44
User entered '1'	System	13 Nov 2020 15:16:06

US3522297

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	17 Dec 2020 21:05:49

US3522297

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '17 Dec 2020'	(b) (4) Yaman Ahmed (b) (4)	17 Dec 2020 21:05:49

US3522297

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	17 Dec 2020 21:05:49

US3522297

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure'	(b) (4) Yaman Ahmed (b) (4)	17 Dec 2020 21:05:49

US3522297

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	17 Dec 2020 21:05:54

US3522297

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User entered '1'	System	17 Dec 2020 21:05:54

US3522297

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:16:23

US3522297

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:16:23

US3522297

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:16:23

US3522297

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered "'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'"	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:16:23

US3522297

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:16:27

US3522297

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User entered '1'	System	15 Jan 2021 20:16:27

US3522297

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 18:36:40

US3522297

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User entered '16 Feb 2021' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	16 Feb 2021 22:39:20
User entered '15 Feb 2021'	(b) (4), (b) (6)	15 Feb 2021 18:36:40

US3522297

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4) Yaman Ahmed (b) (4)	16 Feb 2021 22:39:20
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	15 Feb 2021 18:36:40

US3522297

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
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)	16 Feb 2021 22:39:20
User entered 'left voicemail'	(b) (4), (b) (6)	15 Feb 2021 18:36:40

US3522297

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	16 Feb 2021 22:39:26

US3522297

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User entered '1'	System	16 Feb 2021 22:39:26

US3522297

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:38:38

US3522297

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:38:38

US3522297

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:38:38

US3522297

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User entered 'VISIT4'	System	26 Mar 2021 12:38:38

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	31 Mar 2021 15:12:30

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '26 Mar 2021'	(b) (4) Yaman Ahmed (b) (4)	31 Mar 2021 15:12:30

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '08:18'	(b) (4) Yaman Ahmed (b) (4)	31 Mar 2021 15:12:30

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User entered '26 Mar 2021 08:18'	System	31 Mar 2021 15:12:30

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '97.4' F	(b) (4) Yaman Ahmed (b) (4)	31 Mar 2021 15:12:30

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered 'Other (Other)'	(b) (4) Yaman Ahmed (b) (4)	31 Mar 2021 15:12:30

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered 'temporal'	(b) (4) Yaman Ahmed (b) (4)	31 Mar 2021 15:12:30

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '51'	(b) (4) Yaman Ahmed (b) (4)	31 Mar 2021 15:12:30

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User entered 'bpm'	System	31 Mar 2021 15:12:30

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '14'	(b) (4) Yaman Ahmed (b) (4)	31 Mar 2021 15:12:30

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User entered 'breaths/min'	System	31 Mar 2021 15:12:30

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '113'	(b) (4) Yaman Ahmed (b) (4)	31 Mar 2021 15:12:30

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User entered 'mmHg'	System	31 Mar 2021 15:12:30

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '74'	(b) (4) Yaman Ahmed (b) (4)	31 Mar 2021 15:12:30

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User entered 'mmHg'	System	31 Mar 2021 15:12:30

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01

US3522297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01

US3522297

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:38:45

US3522297

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:38:45

US3522297

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:38:55

US3522297

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:38:55

US3522297

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '08:30'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:38:55

US3522297

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User entered '26 Mar 2021 08:30'	System	26 Mar 2021 12:38:55

US3522297

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:39:00

US3522297

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:30:01
User entered '1'	System	26 Mar 2021 12:39:00

US3522297

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:05:43

US3522297

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:52
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:05:43

US3522297

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:05:43

US3522297

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:52
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:05:43

US3522297

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:05:47

US3522297

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 17:05:47

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:52:01

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:20
User entered '18 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	18 Sep 2020 12:18:37

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:52:01

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:20
User entered '08:18'	Sharon Mathys (b) (4) (b) (4)	18 Sep 2020 12:18:37

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:52:01

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:01
User entered '18 Sep 2020 08:18'	System	18 Sep 2020 12:18:37

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:52:01

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:20
User entered 'Safety Call (Safety Call)'	Sharon Mathys (b) (4) (b) (4)	18 Sep 2020 12:18:37

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:52:01

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	18 Sep 2020 14:10:58
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	18 Sep 2020 12:18:37

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 1 (Day 1)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

Date

Audit	User	Time (GMT)	
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12	
User closed query 'Per source in EPIC note for illness visit, it states that subject's symptoms started on 17Sep2020 "developed minimal cough on 17Sep2020...". Please kindly add a different entry to capture symptoms on 17Sep2020.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:53:55	
User signature succeeded.	(b) (4), (b) (6)	21 Apr 2021 18:53:52	
Query 'Per source in EPIC note for illness visit, it states that subject's symptoms started on 17Sep2020 "developed minimal cough on 17Sep2020...". Please kindly add a different entry to capture symptoms on 17Sep2020.' answered with 'updated' (Site from CRA).	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30	
DataPoint Un-verified.	(b) (4)	(b) (4), (b) (6)	19 Feb 2021 13:33:03
User entered '17 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 13:32:57	
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 19:46:26	
User opened query 'Per source in EPIC note for illness visit, it states that subject's symptoms started on 17Sep2020 "developed minimal cough on 17Sep2020...". Please kindly add a different entry to capture symptoms on 17Sep2020.' (Site from CRA).	(b) (4), (b) (6)	15 Feb 2021 19:44:09	
User closed query 'Per source start date of symptom should be 17SEP2020 as source indicates minimal cough on this date. Please review and advise.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 00:45:40	
User closed query 'Per CDM: Please confirm initial start date of symptoms and Contact Date are the same (18SEP2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 01:46:58	
User entered '18 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 18:18:42	
Comment added 'mistaken. first date not entered into symptom log. First symptom was 17 sep but we contacted and did illness visit on 18 sep'.	(b) (4)	Sharon Mathys (b) (4)	10 Nov 2020 18:17:39

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

Date

Audit	User	Time (GMT)
Query 'Per source start date of symptom should be 17SEP2020 as source indicates minimal cough on this date. Please review and advise.' answered with 'changed. mistaken entry' (Site from CRA).	Sharon Mathys (b) (4) (b) (4)	10 Nov 2020 18:15:36
Query 'Per CDM: Please confirm initial start date of symptoms and Contact Date are the same (18SEP2020) or update accordingly' answered with 'Changed. Contact date was 18 Sep (when we were notified.) Symptoms started day earlier 17 sep 2020' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	10 Nov 2020 18:15:26
User entered '17 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	10 Nov 2020 18:14:51
User opened query 'Per source start date of symptom should be 17SEP2020 as source indicates minimal cough on this date. Please review and advise.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 15:09:37
User opened query 'Per CDM: Please confirm initial start date of symptoms and Contact Date are the same (18SEP2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:55:57
User entered '18 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:46:28
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 18:18:42
User entered '1' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	10 Nov 2020 18:14:51
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:46:30
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	10 Nov 2020 18:14:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	10 Nov 2020 18:14:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:12:18
User entered '98'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 19:46:32
User closed query 'Per source review, vital temperature on 18Sep2020 at 1550hrs was 98.1 F. Please review and update' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 00:45:57
User entered '98.1' F reason for change: Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 18:18:42
Query 'Per source review, vital temperature on 18Sep2020 at 1550hrs was 98.1 F. Please review and update' answered with 'assessment was not done on that day. unsure where value came from. Removed' (Site from CRA).	Sharon Mathys (b) (4)	10 Nov 2020 18:16:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 18:14:51
User opened query 'Per source review, vital temperature on 18Sep2020 at 1550hrs was 98.1 F. Please review and update' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 15:12:16
User entered '100.5' F	Sharon Mathys (b) (4)	22 Sep 2020 11:29:19

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:12:20
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:12:23
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:12:25
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:12:27
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:12:29
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:12:31
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:12:33
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:12:34
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:12:35
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:12:37
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:12:42
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:12:44
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:12:45
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:12:47
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:12:48
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:12:49
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:19

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
User closed query 'Per CDM RQ: Please note that data for Symptom Day 2 (18SEP2020) is not updated. Kindly verify data and add entry to Symptom Log. If Not Done, please check Not Done for the applicable Symptom Day and Date.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 06:35:45
Query 'Per CDM RQ: Please note that data for Symptom Day 2 (18SEP2020) is not updated. Kindly verify data and add entry to Symptom Log. If Not Done, please check Not Done for the applicable Symptom Day and Date.' answered with 'Please note that data for Symptom Day 2 was added to the list, per moderna as the order of the lines is not important. Please check the log before reopening queries.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	18 Mar 2021 11:17:29
User closed query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 19Sep2020. Please review data and consider updating to 'Day 3' 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 07:49:18
User opened query 'Per CDM RQ: Please note that data for Symptom Day 2 (18SEP2020) is not updated. Kindly verify data and add entry 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 07:48:01
User closed query 'Per CDM: Per sponsor review, please verify data and add entry for Symptom Day 2 (18Sep2020) 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 07:48:01
Query 'Per CDM: Per sponsor review, please verify data and add entry for Symptom Day 2 (18Sep2020) 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 13:52:12

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 19Sep2020. Please review data and consider updating to 'Day 3' 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). Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:52:08
	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:51:58
User opened query 'Per CDM: Per sponsor review, please verify data and add entry for Symptom Day 2 (18Sep2020) 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 22:21:24
User opened query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 19Sep2020. Please review data and consider updating to 'Day 3' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	14 Mar 2021 22:20:28
	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 2 (Day 2)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered '19 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered '98'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered '99.1' F	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:52:25
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:29:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 3 (Day 3)'	(b) (4) Sharon Mathys (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered '20 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered '99'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered '98.2' F	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:14:46
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 4 (Day 4)'	(b) (4) Sharon Mathys (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered '99'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered '97.4' F	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:54:18
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:15:28
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:09:59

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 5 (Day 5)'	(b) (4) Sharon Mathys (b) (4)	24 Sep 2020 18:11:06

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered '22 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered '99'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	24 Sep 2020 18:11:06

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered '96.2' F	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:06

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 6 (Day 6)'	(b) (4) Sharon Mathys (b) (4)	24 Sep 2020 18:11:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:42
User entered '23 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:49
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:51
User entered '98'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 02:25:04
User closed query 'Per source temperature is documented as 96.8 F. Please review and update.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 02:25:03
Query 'Per source temperature is documented as 96.8 F. Please review and update.' answered with 'entry error. corrected' (Site from CRA).	Sharon Mathys (b) (4)	10 Nov 2020 18:22:42
User entered '96.8' F reason for change: Data Entry Error	(b) (4)	10 Nov 2020 18:22:33
User opened query 'Per source temperature is documented as 96.8 F. Please review and update.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 15:17:21
User entered '95.8' F	Sharon Mathys (b) (4)	24 Sep 2020 18:11:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:17:31
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:17:32
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:17:34
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:17:35
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:17:37
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:17:38
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:17:40
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:17:43
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:17:45
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:54:48
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:17:47
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:17:48
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:17:49
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:17:51
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:17:53
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:17:55
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:17:57
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 7 (Day 7)'	(b) (4) Sharon Mathys (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered '24 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered '95'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered '97.8' F	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:59:02
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:11
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:00

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 8 (Day 8)'	(b) (4) Sharon Mathys (b) (4)	05 Oct 2020 11:52:39

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Form: Symptom Log (8)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered '25 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

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Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered '0'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered '99'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	05 Oct 2020 11:52:39

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered '97.1' F	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

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Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:59:21
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:59:15
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:18:48
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:52:39

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 9 (Day 9)'	(b) (4) Sharon Mathys (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered '26 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered '0'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered '96'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered '96.8' F	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:00
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 10 (Day 10)'	(b) (4) Sharon Mathys (b) (4)	05 Oct 2020 11:54:10

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered '27 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered '0'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered '99'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	05 Oct 2020 11:54:10

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered '97.1' F	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:10

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 11 (Day 11)'	(b) (4) Sharon Mathys (b) (4)	05 Oct 2020 11:54:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered '28 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered '97'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	05 Oct 2020 11:54:43

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered '97.3' F	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:54:43

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 12 (Day 12)'	(b) (4) Sharon Mathys (b) (4)	05 Oct 2020 14:13:14

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered '29 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered '0'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered '98'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	05 Oct 2020 14:13:14

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered '97.5' F	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:30
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:13:14

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 13 (Day 13)'	(b) (4) Sharon Mathys (b) (4)	05 Oct 2020 14:17:45

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered '30 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered '0'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered '97'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	05 Oct 2020 14:17:45

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered '98.3' F	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:17:45

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 14 (Day 14)'	(b) (4) Sharon Mathys (b) (4)	05 Oct 2020 14:18:29

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Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered '1 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered '0'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered '99'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	05 Oct 2020 14:18:29

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered '98.2' F	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 15 (Day 15)'	(b) (4) Sharon Mathys (b) (4)	05 Oct 2020 14:19:25

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered '2 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered '0'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered '97'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	05 Oct 2020 14:19:25

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered '97.2' F	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 16 (Day 16)'	(b) (4) Sharon Mathys (b) (4)	05 Oct 2020 14:20:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered '3 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered '0'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered '96'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	05 Oct 2020 14:20:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered '98.1' F	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 18 (Day 18)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 17 (Day 17)'	(b) (4) Sharon Mathys (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered '4 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered '0'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered '97'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered '97.8' F	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:21:08

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 19 (Day 19)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 18 (Day 18)'	(b) (4) Sharon Mathys (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered '05 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered '98'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered '96.6' F	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:47:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 20 (Day 20)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 19 (Day 19)'	(b) (4) Sharon Mathys (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered '6 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered '0'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered '96'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered '97.8' F	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:29:53

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 21 (Day 21)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 20 (Day 20)'	(b) (4) Sharon Mathys (b) (4)	19 Oct 2020 14:31:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered '07 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered '0'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered '98'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	19 Oct 2020 14:31:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered '97.6' F	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:22
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:16

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
Signature has been broken.	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User entered 'Day 22 (Day 22)' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	15 Mar 2021 13:51:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Day 21 (Day 21)'	(b) (4) Sharon Mathys (b) (4)	19 Oct 2020 14:31:57

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
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 16OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 01:48:47
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 16OCT2020. Please reconcile or clarify.' answered with 'Site was under the assumption that Illness visit with a positive test must have a day 28 visit, but illness period can be exited early with two negative saliva tests and no symptoms after at least 14 days. Since saliva was negative twice and no symptoms, site stopped daily telemedicine visits.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	10 Nov 2020 18:21:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
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 16OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:56:23
User entered '08 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered '0'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered '96'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	19 Oct 2020 14:31:57

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered '98.4' F	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:04:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 19:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:31:57

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered 'Day 2 (Day 2)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered '18 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered missing code ND - Not Done.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
User entered '%'	System	15 Mar 2021 13:50:42

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered missing code ND - Not Done.	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:52:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:13:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 13:50:42

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Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

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[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:31
User entered '18 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:28:09

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Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

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[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:31
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:28:09

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Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:52:01

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:31
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)	25 Sep 2020 09:22:46
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 'Has been done' (Site from System).	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 20:01:46
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	22 Sep 2020 11:28:09
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:28:09

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Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:52:01

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:31
User entered '18 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:28:09

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Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:52:01

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:31
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:28:09

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Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:52:01

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:31
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:28:09

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Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:52:01

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:31
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:28:09

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Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:52:01

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:31
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:28:09

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Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:52:01

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:31
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:28:09

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Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:52:01

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:22
User entered '1'	System	22 Sep 2020 11:28:09

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Form: Covid-19 Severity Assessment

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

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)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:09:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User closed query 'Per CDM: it appears 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is recorded as No but data is present. Please reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 09:03:30
Query 'Per CDM: it appears 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is recorded as No but data is present. Please reconcile' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	19 Jan 2021 15:27:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 15:27:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 15:27:10
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Jan 2021 15:27:10
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 15:26:56
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	19 Jan 2021 15:26:56
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Jan 2021 15:26:56
User opened query 'Per CDM: it appears 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is recorded as No but data is present. Please reconcile' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 16:49:03
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Form: Covid-19 Severity Assessment

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:09:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	19 Jan 2021 15:26:56
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Jan 2021 15:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Generated On: 11 Aug 2021 22:52:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Form: Covid-19 Severity Assessment

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:09:56
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User closed query 'Per CDM; Please review Evidence of Shock section of this form as it appears responses are missing and update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 09:04:01
DataPoint Un-verified.	Sharon Mathys (b) (4)	19 Jan 2021 15:28:06
User entered empty; reason for change Data Entry Error	(b) (4)	19 Jan 2021 15:28:06
Query 'Per CDM; Please review Evidence of Shock section of this form as it appears responses are missing and update accordingly.' answered with 'query does not make sense. please clarify' (Site from DM).	Sharon Mathys (b) (4)	19 Jan 2021 15:27:51
User opened query 'Per CDM; Please review Evidence of Shock section of this form as it appears responses are missing and update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 16:50:04
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered 'No (N)'	Sharon Mathys (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

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Generated On: 11 Aug 2021 22:52:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

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Generated On: 11 Aug 2021 22:52:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:52:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:02:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:36:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:52:01

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:10:06
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:21:48
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	09 Mar 2021 19:04:51

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:52:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:52:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:30:06
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:52:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:30:06
User entered '20 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:52:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:52:01

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:30:06
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 18:13:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 18:13:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:30
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 11:35:47
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:52:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:30:06
User entered '22 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:30
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:52:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:52:01

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:30:06
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 18:13:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 18:13:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:30
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 11:35:47
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:52:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:30:06
User entered '24 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 18:13:30
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:52:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:52:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:30:06
User entered 'Yes (Y)' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:56:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 07:34:03
Query 'Data is required. Please complete.' answered with 'Please leave blank until we fill in' (Site from System).	Sharon Mathys (b) (4) (b) (4)	26 Sep 2020 20:42:38
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 11:35:47
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:52:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:30:06
User entered '26 Sep 2020' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:56:25
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:52:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:52:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:30:06
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 08:45:27
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	29 Oct 2020 12:25:38
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:31:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:12:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 07:34:23
Query 'Data is required. Please complete.' answered with 'please leave blank until we fill in' (Site from System).	Sharon Mathys (b) (4) (b) (4)	26 Sep 2020 20:42:48
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 11:35:47
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:52:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:30:06
User entered '1 Oct 2020' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:12:10
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:52:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:52:01

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User closed query 'Per CDM: it appears a Convalescence Visit Day 28 has occurred on 16OCT2020; however, there is no Saliva record present for Day 28. Please reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 01:47:38
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:30:06
Query 'Per CDM: it appears a Convalescence Visit Day 28 has occurred on 16OCT2020; however, there is no Saliva record present for Day 28. Please reconcile.' answered with 'CoI did not take saliva.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	10 Nov 2020 13:52:26
User opened query 'Per CDM: it appears a Convalescence Visit Day 28 has occurred on 16OCT2020; however, there is no Saliva record present for Day 28. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:54:30
User entered 'Yes (Y)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	29 Oct 2020 12:25:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 07:36:48
Query 'Data is required. Please complete.' answered with 'please leave blank until we fill in' (Site from System).	Sharon Mathys (b) (4) (b) (4)	26 Sep 2020 20:42:57
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 11:35:47
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:52:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:30:06
User entered '08 Oct 2020' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	29 Oct 2020 12:25:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:52:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:52:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:03:41
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 22:32:38
DataPoint Un-verified.	(b) (4)	
	Sharon Mathys (b) (4)	28 Apr 2021 17:43:51
Signature has been broken.	(b) (4)	
	Sharon Mathys (b) (4)	28 Apr 2021 17:43:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	28 Apr 2021 17:43:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 15:30:06
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 13:52:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	28 Sep 2020 07:37:04
Query 'Data is required. Please complete.' answered with 'Please leave blank until we fill in' (Site from System).	Sharon Mathys (b) (4)	26 Sep 2020 20:43:09
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 11:35:47
User entered empty.	Sharon Mathys (b) (4)	22 Sep 2020 11:35:47
	(b) (4)	

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:52:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:30:06
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:47

US3522297

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:59:49
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:28:24

US3522297

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:59:49
User entered '18 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:28:24

US3522297

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:59:49
User entered 'Clinic (Clinic)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:28:24

US3522297

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User entered 'SICKD1'	System	22 Sep 2020 11:28:24

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:59:56
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:59:56
User entered '18 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:59:56
User entered '15:50'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User entered '18 Sep 2020 15:50'	System	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User closed query 'Per CDM: Per CCG, data to be entered for "height and weight". Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 03:51:31
Query 'Per CDM: Per CCG, data to be entered for "height and weight". Please update accordingly. ' answered with 'Per protocol, height and weight are not mentioned as necessary for illness visits.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	05 Nov 2020 14:34:00
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)	05 Nov 2020 11:45:13
Query 'Per CDM: Per CCG, data to be entered for "height and weight". Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 10:34:52
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)	22 Oct 2020 09:50:22
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:59:56
User entered missing code ND - Not Done.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:52:29
DataPoint set to visible.	System	22 Sep 2020 11:28:24

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User closed query 'Per CDM: Per CCG, data to be entered for "height and weight". Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 03:51:33
Query 'Per CDM: Per CCG, data to be entered for "height and weight". Please update accordingly. ' answered with 'Per protocol, height and weight are not mentioned as necessary for illness visits.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	05 Nov 2020 14:34:03
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)	05 Nov 2020 11:45:23
Query 'Per CDM: Per CCG, data to be entered for "height and weight". Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 10:34:54
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)	22 Oct 2020 09:50:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:59:56
User entered missing code ND - Not Done.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:52:29
DataPoint set to visible.	System	22 Sep 2020 11:28:24

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:59:56
User entered '98.1' F	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:59:56
User entered 'Oral (Oral)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:59:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:59:56
User entered '78'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User entered 'bpm'	System	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:59:56
User entered '16'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User entered 'breaths/min'	System	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:59:56
User entered '113'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User entered 'mmHg'	System	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:59:56
User entered '76'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User entered 'mmHg'	System	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31

US3522297

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:00:05
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:40

US3522297

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:00:05
User entered '18 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:30:40

US3522297

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:52:01

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:01:20
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:52:40

US3522297

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:52:01

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:01:20
User entered '18 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:52:40

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:26:37
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:19:32

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:26:37
User entered '16 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:19:32

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:26:37
User entered 'Clinic (Clinic)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:19:32

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User entered 'SICKD28'	System	19 Oct 2020 14:19:32

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:27:09
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:27:09
User entered '16 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:27:09
User entered '08:15'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User entered '16 Oct 2020 08:15'	System	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:27:09
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)	30 Oct 2020 11:29:18
Query 'Per CDM: Per CCG, data to be entered for "height and weight". Please update accordingly. ' answered with 'Height and weight were not done. It was understood per protocol height and weight were done for BMI calculation only which was on screening visit.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	28 Oct 2020 17:23:48
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)	28 Oct 2020 12:04:38
User entered missing code ND - Not Done.	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:21:41
DataPoint set to visible.	System	19 Oct 2020 14:19:32

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:27:09
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)	30 Oct 2020 11:29:21
Query 'Per CDM: Per CCG, data to be entered for "height and weight". Please update accordingly. ' answered with 'Height and weight were not done. It was understood per protocol height and weight were done for BMI calculation only which was on screening visit.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	28 Oct 2020 17:23:51
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)	28 Oct 2020 12:04:48
User entered missing code ND - Not Done.	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:21:41
DataPoint set to visible.	System	19 Oct 2020 14:19:32

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:27:09
User entered '97.4' F	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:27:09
User entered 'Oral (Oral)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:27:09
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:27:09
User entered '58'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User entered 'bpm'	System	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:27:09
User entered '17'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User entered 'breaths/min'	System	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:27:09
User entered '121'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:21:41

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User entered 'mmHg'	System	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:27:09
User entered '79'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User entered 'mmHg'	System	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:27:17
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:19:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:27:17
User entered '16 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:19:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:52:01

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:27:27
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:20:03

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:52:01

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:09:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:27:27
User entered '16 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:20:03

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:46:02

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:46:02

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:46:02

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 13:46:02

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:52:01

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:46:13

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:52:01

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
User entered '0'	(b) (4) Sharon Mathys (b) (4)	17 Mar 2021 12:52:13
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 06:18:42

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:52:01

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:46:13

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:52:01

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:13:03
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Sharon Mathys (b) (4)	17 Mar 2021 12:52:13
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 06:18:42

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:52:01

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:46:13

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:52:01

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:46:13

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:52:01

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:46:13

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:52:01

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:46:13

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:52:01

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:46:13

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:52:01

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered '1'	System	22 Jan 2021 13:46:13

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:52:01

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered '1'	System	22 Jan 2021 13:46:13

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered empty.	System	22 Jan 2021 13:49:47
DataPoint set to visible.	System	22 Jan 2021 13:46:13

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:47

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered empty.	System	22 Jan 2021 13:49:47
DataPoint set to visible.	System	22 Jan 2021 13:46:13

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:47

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '08:20'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered '22 Jan 2021 08:20'	System	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:47

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '64'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'bpm'	System	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '16'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'breaths/min'	System	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '140'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'mmHg'	System	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '88'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'mmHg'	System	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:47

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:52:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered empty.	System	22 Jan 2021 13:49:47
DataPoint set to visible.	System	22 Jan 2021 13:46:13

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Jan 2021 14:41:59

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:41:59

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:41:59

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '09:40'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:41:59

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered '22 Jan 2021 09:40'	System	22 Jan 2021 14:41:59

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:41:59

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:41:59

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:41:59

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '61'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:41:59

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'bpm'	System	22 Jan 2021 14:41:59

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '16'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:41:59

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'breaths/min'	System	22 Jan 2021 14:41:59

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '129'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:41:59

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'mmHg'	System	22 Jan 2021 14:41:59

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '80'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:41:59

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'mmHg'	System	22 Jan 2021 14:41:59

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:02

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:49:02

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:15:55

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:15:55

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

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)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:15:55

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'mRNA-1273'	System	22 Jan 2021 14:15:55
DataPoint set to visible.	System	22 Jan 2021 13:46:13

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:15:55

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '09:10'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:15:55

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered '22 Jan 2021 09:10'	System	22 Jan 2021 14:15:55

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:15:55

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'ONCE'	System	22 Jan 2021 14:15:55

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'INTRAMUSCULAR'	System	22 Jan 2021 14:15:55

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:48:34

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:48:34

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '08:25'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:48:34

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered '22 Jan 2021 08:25'	System	22 Jan 2021 13:48:34

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:52:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:48:46

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:52:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:48:46

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:52:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '08:30'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:48:46

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:52:01

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered '22 Jan 2021 08:30'	System	22 Jan 2021 13:48:46

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 13:48:54

US3522297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered '1'	System	22 Jan 2021 13:48:54

US3522297

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:21:20

US3522297

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:21:20

US3522297

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:21:20

US3522297

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'call completed'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:21:20

US3522297

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:21:24

US3522297

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered '1'	System	29 Jan 2021 14:21:24

US3522297

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered '1'	System	29 Jan 2021 14:21:24
DataPoint set to visible.	System	29 Jan 2021 14:21:24

US3522297

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:34:10

US3522297

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:34:10

US3522297

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:34:10

US3522297

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'OLD29'	System	19 Feb 2021 13:34:10

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '08:31'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered '19 Feb 2021 08:31'	System	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '63'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'bpm'	System	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '16'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'breaths/min'	System	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '128'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'mmHg'	System	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '75'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'mmHg'	System	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 14:26:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 14:26:20
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	19 Feb 2021 14:26:20
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 13:49:03
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '09:16' reason for change: New Information	(b) (4), (b) (6)	19 Feb 2021 14:26:20
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered '19 Feb 2021 09:16'	System	19 Feb 2021 14:26:20
User entered empty.	System	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '98.2' F reason for change: New Information	(b) (4), (b) (6)	19 Feb 2021 14:26:20
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Other (Other)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	19 Feb 2021 14:26:20
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'temporal' reason for change: Per Query Resolution	(b) (4)	19 Feb 2021 14:26:20
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '67' reason for change: New Information	(b) (4) (b) (4), (b) (6)	19 Feb 2021 14:26:20
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'bpm'	System	19 Feb 2021 14:26:20
User entered empty.	System	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '14' reason for change: New Information	(b) (4), (b) (6)	19 Feb 2021 14:26:20
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'breaths/min'	System	19 Feb 2021 14:26:20
User entered empty.	System	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '124' reason for change: New Information	(b) (4) (b) (4), (b) (6)	19 Feb 2021 14:26:20
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'mmHg'	System	19 Feb 2021 14:26:20
User entered empty.	System	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '82' reason for change: New Information	(b) (4), (b) (6)	19 Feb 2021 14:26:20
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'mmHg'	System	19 Feb 2021 14:26:20
User entered empty.	System	19 Feb 2021 13:49:03

US3522297

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:34:26

US3522297

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:34:26

US3522297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:48:17

US3522297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:48:17

US3522297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

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)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:48:17

US3522297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'mRNA-1273'	System	19 Feb 2021 13:48:17
DataPoint set to visible.	System	29 Jan 2021 14:21:24

US3522297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:48:17

US3522297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '08:46'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:48:17

US3522297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered '19 Feb 2021 08:46'	System	19 Feb 2021 13:48:17

US3522297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:48:17

US3522297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'ONCE'	System	19 Feb 2021 13:48:17

US3522297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:52:01

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'INTRAMUSCULAR'	System	19 Feb 2021 13:48:17

US3522297

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:48:23

US3522297

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered '1'	System	19 Feb 2021 13:48:23

US3522297

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:36:54

US3522297

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered '01 Mar 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:40:15
User entered '26 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 19:36:54

US3522297

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:40:15
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	26 Feb 2021 19:36:54

US3522297

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:52:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'See source note. No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:40:15
User entered 'Left voicemail'	(b) (4), (b) (6)	26 Feb 2021 19:36:54

US3522297

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:37:00

US3522297

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:52:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered '1'	System	26 Feb 2021 19:37:00

US3522297

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:39:14

US3522297

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:39:14

US3522297

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:39:14

US3522297

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:52:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'OLD57'	System	26 Mar 2021 12:39:14

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:39:49

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:39:49

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '08:18'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:39:49

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered '26 Mar 2021 08:18'	System	26 Mar 2021 12:39:49

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '97.4' F	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:39:49

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:39:49

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:39:49

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '51'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:39:49

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'bpm'	System	26 Mar 2021 12:39:49

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '14'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:39:49

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'breaths/min'	System	26 Mar 2021 12:39:49

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '113'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:39:49

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'mmHg'	System	26 Mar 2021 12:39:49

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '74'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:39:49

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered 'mmHg'	System	26 Mar 2021 12:39:49

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19

US3522297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:52:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19

US3522297

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:39:58

US3522297

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:52:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:39:58

US3522297

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:40:08

US3522297

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:40:08

US3522297

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:38:43
User entered '08:30'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:40:08

US3522297

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:52:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:02:19
User entered '26 Mar 2021 08:30'	System	26 Mar 2021 12:40:08

US3522297

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:52:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:34:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 14:35:09

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:41
User entered 'USA-US131-2020-mRNA-1273-P301000004'	System	23 Sep 2020 11:47:36
User entered 'New'	(b) (4), (b) (6)	23 Sep 2020 11:47:36

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:19
User coded data point as SOC: Infections and infestations, HLG: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 19:29:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 19:29:19
User closed query 'Per CDM: COVID-19 symptoms should not be considered as AE which comes under COVID diagnosis. Please reconcile and add to the Covid-19 Assessment .' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 11:50:08
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (MILD COUGH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 11:50:02
Query 'Per CDM: COVID-19 symptoms should not be considered as AE which comes under COVID diagnosis. Please reconcile and add to the Covid-19 Assessment .' answered with 'Covid-19 assessment present ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 20:32:31
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (MILD COUGH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' answered with 'updated to fix overlap ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 20:22:13
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (MILD COUGH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:56:30

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 respiratory infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 00:04:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 00:04:35
Data point term sent to Coder	System	21 Oct 2020 13:33:33
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	21 Oct 2020 13:33:00
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	21 Oct 2020 13:33:00
User entered 'SYMPTOMATIC COVID-19 INFECTION' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	21 Oct 2020 13:33:00
User opened query 'Per CDM: COVID-19 symptoms should not be considered as AE which comes under COVID diagnosis. Please reconcile and add to the Covid-19 Assessment .' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 12:26:17
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:58:55
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 11:56:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 11:56:42
Data point term sent to Coder	System	22 Sep 2020 11:35:56
User entered 'Symptomtic COVID-19 Infection' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:35:28
Data point term sent to Coder	System	22 Sep 2020 11:34:56
User entered 'COVID-19'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered '18 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 11:34:03

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:38:03
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:32:29
User closed query 'PV Query: Please consider updating the event end date to the date the subject no longer had COVID-19 symptoms.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 19:33:00
Query 'PV Query: Please consider updating the event end date to the date the subject no longer had COVID-19 symptoms.' answered with 'updated' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:14:21
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:14:11
User entered '26 Sep 2020' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:14:11
User opened query 'PV Query: Please consider updating the event end date to the date the subject no longer had COVID-19 symptoms.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:07:45
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:58:55
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)	05 Oct 2020 14:27:21
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 'Patient contacted. All Sx resolved on 9/30, still feels slightly "tired".' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 14:38:53
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Oct 2020 14:38:48
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	02 Oct 2020 14:38:48
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Oct 2020 14:38:03

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:38:03
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)	29 Sep 2020 16:56:00
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 11:34:03

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
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 19:59:32
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	22 Sep 2020 11:34:03
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:19
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 update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 22:13:26
User closed query 'Per MM: Action taken with IP is "none". Please confirm that study drug was discontinued per protocol 7.2.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 11:51:30
Query 'Per MM: Action taken with IP is "none". Please confirm that study drug was discontinued per protocol 7.2.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 20:29:39
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 update action taken to withdrawn.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 20:29:35
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	21 Oct 2020 13:32:29
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	21 Oct 2020 13:32:21
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	21 Oct 2020 13:32:21
User opened query 'Per MM: Action taken with IP is "none". Please confirm that study drug was discontinued per protocol 7.2.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:22:15
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 update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:54:30
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:58:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

Action taken with investigational product

Audit	User	Time (GMT)
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)	24 Sep 2020 03:33:59
User entered 'None (NONE)' reason for change: Per Query Resolution	Sharon Mathys (b) (4)	23 Sep 2020 19:59:32
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 'Asked to put Diagnosed Covid-19 infection in Adverse events. Please clarify instructions if that is not what should be done.' (Site from System).	Sharon Mathys (b) (4)	22 Sep 2020 11:35:14
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	22 Sep 2020 11:34:03
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Sharon Mathys (b) (4)	22 Sep 2020 11:34:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

None

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:32:29
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 12:26:42
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:32:02
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:31:34
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:31:34
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 03:24:31
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:32:29
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:31:34
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:55
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:19
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	21 Oct 2020 13:36:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	21 Oct 2020 13:36:26
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:58:55
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)	05 Oct 2020 14:27:26
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:54:09
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 'Updated.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 14:53:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:38:48
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)	29 Sep 2020 16:55:36
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:19
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	21 Oct 2020 13:36:26
User entered empty; reason for change Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	21 Oct 2020 13:36:26
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:58:55
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	02 Oct 2020 14:54:28
User entered 'Slight fatigue, no medication required.' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:54:28
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	02 Oct 2020 14:54:09
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User closed query 'Per DM CLR: SAE Narrative = PATIENT TOOK 1 ASPIRIN DAILY (325 MG) FROM 9/18 - 9/26. However, ConMed frequency in CM eCRF is "as needed". Please review and determine if a separate entry should be recorded. Update eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 03:14:33
Query 'Per DM CLR: SAE Narrative = PATIENT TOOK 1 ASPIRIN DAILY (325 MG) FROM 9/18 - 9/26. However, ConMed frequency in CM eCRF is "as needed". Please review and determine if a separate entry should be recorded. Update eCRF as appropriate. Otherwise, clarify. ' answered with 'updated ecrf for clarity and added another aspirin' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:12:10
User opened query 'Per DM CLR: SAE Narrative = PATIENT TOOK 1 ASPIRIN DAILY (325 MG) FROM 9/18 - 9/26. However, ConMed frequency in CM eCRF is "as needed". Please review and determine if a separate entry should be recorded. Update eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 03:46:12
User closed query 'Per DM CLR: SAE Narrative = PATIENT TOOK 1 ASPIRIN DAILY (325 MG) FROM 9/18 - 9/26. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 11:52:33
Query 'Per DM CLR: SAE Narrative = PATIENT TOOK 1 ASPIRIN DAILY (325 MG) FROM 9/18 - 9/26. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated in ConMed' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 20:31:42
User opened query 'Per DM CLR: SAE Narrative = PATIENT TOOK 1 ASPIRIN DAILY (325 MG) FROM 9/18 - 9/26. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:56:22

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:58:55
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 14:27:33
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 14:27:31
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)	05 Oct 2020 14:27:29

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Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ON MONDAY, SEPTEMBER 7TH. PT'S WIFE STARTED TO FEEL ILL AND SICK, SO SHE LATER WENT TO GET TESTED ON SEPTEMBER 8TH. RESULTS CAME BACK ON THE 10TH STATING NEGATIVE. SHE FELT BETTER ON SATURDAY (12TH). SUNDAY(13TH) PT AND WIFE WENT TO GET DINNER AT AN OUTDOOR RESTAURANT. ON MONDAY (14TH) PT'S WIFE LOST HER SENSE OF SMELL AND WENT TO GET ANOTHER TEST SAME DAY. COVID TEST RESULT CAME BACK POSITIVE ON THE 16TH. THURSDAY (17TH) MORNING PATIENT GOT TESTED, RESULTS CAME BACK POSITIVE FRIDAY (18TH). SLIGHT COUGH FOR 3 DAYS, TEMPERATURE WAS HIGHEST AT 100F ON FRIDAY(18TH). MONDAY (21ST) PT LOST SENSE OF SMELL AND TASTE, STARTED FEELING BETTER BY FRIDAY (25TH). ON 26TH/27TH, PT REPORTS HAVING SENSATIONS INSIDE HIS NOSE, AS HIS SENSE OF TASTE AND SMELL WAS FULLY COMING BACK. PATIENT REPORTS HEADACHES, AND FATIGUE, NO SOB. PATIENT TOOK 1 ASPIRIN DAILY (325 MG) FROM 9/18 - 9/26. PATIENT QUARANTINED IMMEDIATELY AFTER GETTING TEST RESULTS. No current symptoms other than slight fatigue.' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:55:54
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 'Provided.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 14:53:37
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Provided.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 14:53:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:52:01

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' answered with 'Provided.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 14:53:31
User entered 'On Monday, September 7th. Pt's wife started to feel ill and sick, so she later went to get tested on September 8th. Results came back on the 10th stating negative. She felt better on Saturday (12th). Sunday(13th) Pt and wife went to get dinner at an outdoor restaurant. On Monday (14th) Pt's wife lost her sense of smell and went to get another test same day. COVID test result came back positive on the 16th. Thursday (17th) morning patient got tested, results came back positive Friday (18th). Slight cough for 3 days, temperature was highest at 100F on Friday(18th). Monday (21st) Pt lost sense of smell and taste, started feeling better by Friday (25th). On 26th/27th, pt reports having sensations inside his nose, as his sense of taste and smell was fully coming back. Patient reports headaches, and fatigue, no SOB. Patient took 1 aspirin daily (325 mg) from 9/18 - 9/26. Patient quarantined immediately after getting test results.' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:53:10
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 16:56:37
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 16:56:26
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)	29 Sep 2020 16:55:10
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:34:03

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Folder: Adverse Events

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	22 Sep 2020 11:34:03

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Folder: Adverse Events

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	22 Sep 2020 11:34:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:52:01

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:34:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Aug 2020 14:33:46
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:48:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 17:50:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 17:50:29
Data point term sent to Coder Coding entries removed.	System Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 17:26:06 09 Oct 2020 17:25:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 21:22:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 21:22:45
Data point term sent to Coder User entered 'Aspirin'	System (b) (4), (b) (6)	28 Aug 2020 14:35:00 28 Aug 2020 14:34:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:49
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 14:34:56

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User closed query 'Per DM CLR-RQ: Response does not satisfy query. Please review if AE reporting criteria per protocol has been met. If yes, update to record as adverse event. Otherwise, confirm that this is not a reportable adverse event. Update as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR-RQ: Response does not satisfy query. Please review if AE reporting criteria per protocol has been met. If yes, update to record as adverse event. Otherwise, confirm that this is not a reportable adverse event. Update as appropriate. Otherwise, clarify.' answered with 'not a reportable adverse event' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 09:32:50
User opened query 'Per DM CLR-RQ: Response does not satisfy query. Please review if AE reporting criteria per protocol has been met. If yes, update to record as adverse event. Otherwise, confirm that this is not a reportable adverse event. Update as appropriate. Otherwise, clarify.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	15 Jan 2021 18:57:07
User opened query 'Per DM CLR-RQ: Response does not satisfy query. Please review if AE reporting criteria per protocol has been met. If yes, update to record as adverse event. Otherwise, confirm that this is not a reportable adverse event. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:16:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:35:49
User closed query 'Per DM CLR: Please review Indication and please update to specify the location of several joints that were noted to have aches/pain. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 07:56:41
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the Joint Aches in Several Joints is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Joint Aches in Several Joints did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 07:56:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review Indication and please update to specify the location of several joints that were noted to have aches/pain. Please update as appropriate or provide clarification.' answered with 'matches eDiary entry.' (Site from DM).	Sharon Mathys (b) (4)	30 Oct 2020 17:14:06
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the Joint Aches in Several Joints is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Joint Aches in Several Joints did not meet the AE reporting criteria.' answered with 'in the eDiary' (Site from DM).	Sharon Mathys (b) (4)	30 Oct 2020 17:13:47
User opened query 'Per DM CLR: Please review Indication and please update to specify the location of several joints that were noted to have aches/pain. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:23:48
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the Joint Aches in Several Joints is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Joint Aches in Several Joints did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:23:22
User closed query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:50:04

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'see eDiary' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 17:25:28
User entered 'JOINT Aches in Several Joints' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 17:25:21
User opened query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Sep 2020 12:45:53
User entered 'Joint pain post injection'	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 14:34:56

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:49
User entered '325'	(b) (4), (b) (6)	28 Aug 2020 14:34:56

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:49
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Aug 2020 14:34:56

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:49
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 14:34:56

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:49
User entered 'as needed (PRN)'	(b) (4), (b) (6)	28 Aug 2020 14:34:56

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:49
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 14:34:56

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:49
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 14:34:56

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:49
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 14:34:56

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:49
User entered '22 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 14:34:56

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:49
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 14:34:56

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:49
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 14:34:56

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:10:56
User entered '23 Aug 2020' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:10:56
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:35:49
User entered '26 Sep 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	04 Nov 2020 20:31:25
User entered '23 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 14:34:56

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:35:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 14:34:56

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US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 14:34:56

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 14:34:56

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:52:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 14:34:56

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 07:17:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 07:17:09
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:06:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:06:02
Data point term sent to Coder	System	17 Nov 2020 13:15:30
Data point term sent to Coder	System	17 Nov 2020 13:12:27
User entered 'Aspirin'	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'SYMPTOMATIC COVID-19 Infection' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	17 Nov 2020 13:14:44
User entered 'Symptomatic Covid-19'	(b) (4)	
	Sharon Mathys (b) (4)	17 Nov 2020 13:11:41
	(b) (4)	

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User entered '325'	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User entered empty.	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User entered 'once daily (QD)'	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User entered empty.	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User entered empty.	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '18 Sep 2020'	(b) (4) Sharon Mathys (b) (4)	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User entered '0'	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '26 Sep 2020'	(b) (4) Sharon Mathys (b) (4)	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User entered '1'	System	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User entered '1'	System	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:52:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:10:51
User entered '804 (804)'	System	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:52:01

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:48:10

US3522297

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:52:01

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:09:49
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User entered '18 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:32:55

US3522297

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:52:01

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:09:49
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User entered 'Due to SARS-COV-2 (COVID)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:32:55

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:52:01

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)	29 Apr 2021 08:09:49
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:45:30
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:32:55

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'USA-US131-2020-MRNA-1273-P301000004'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'Paul'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'Kilgore'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered (b) (6) '	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered (b) (6) '	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'MI'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered (b) (6)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:28:36
User entered 'US'	System	23 Sep 2020 11:48:04

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	18 Nov 2020 19:33:46
User entered '3'	System	05 Nov 2020 22:14:16
User entered '2'	System	05 Oct 2020 14:30:17
User entered '1'	System	23 Sep 2020 11:48:04

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'USA-US131-2020-MRNA-1273-P301000004'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'Paul'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'Kilgore'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered (b) (6) '	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered (b) (6) '	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'MI'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered (b) (6)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:28:36
User entered 'US'	System	23 Sep 2020 11:48:04

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	18 Nov 2020 19:33:46
User entered '3'	System	05 Nov 2020 22:14:16
User entered '2'	System	05 Oct 2020 14:30:17
User entered '1'	System	23 Sep 2020 11:48:04

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:52:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
User entered '23/Sep/2020 07:48'	System	23 Sep 2020 11:48:04

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:52:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:28:36
User entered 'l'	(b) (4), (b) (6)	23 Sep 2020 11:48:04

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'USA-US131-2020-MRNA-1273-P301000004'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'Paul'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'Kilgore'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered (b) (6) '	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered (b) (6) '	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'MI'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered (b) (6)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:28:36
User entered 'US'	System	23 Sep 2020 11:48:04

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	18 Nov 2020 19:33:46
User entered '3'	System	05 Nov 2020 22:14:16
User entered '2'	System	05 Oct 2020 14:30:17
User entered '1'	System	23 Sep 2020 11:48:04

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:52:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
User entered '05/Oct/2020 10:30'	System	05 Oct 2020 14:30:17

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:52:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:14:03
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:58:19
User entered '1'	(b) (4), (b) (6)	05 Oct 2020 14:30:17

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'USA-US131-2020-MRNA-1273-P301000004'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'Paul'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'Kilgore'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered (b) (6) '	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered (b) (6) '	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'MI'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered (b) (6)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:28:36
User entered 'US'	System	23 Sep 2020 11:48:04

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	18 Nov 2020 19:33:46
User entered '3'	System	05 Nov 2020 22:14:16
User entered '2'	System	05 Oct 2020 14:30:17
User entered '1'	System	23 Sep 2020 11:48:04

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:52:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:21:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '05/Nov/2020 22:14'	(b) (4) System	05 Nov 2020 22:14:16

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:52:01

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)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:21:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:26
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 22:14:16

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'USA-US131-2020-MRNA-1273-P301000004'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'No (N)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'Paul'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'Kilgore'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered (b) (6) '	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered (b) (6) '	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered 'MI'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:47:58
User entered (b) (6)'	System	23 Sep 2020 11:47:36

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:28:36
User entered 'US'	System	23 Sep 2020 11:48:04

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:52:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	18 Nov 2020 19:33:46
User entered '3'	System	05 Nov 2020 22:14:16
User entered '2'	System	05 Oct 2020 14:30:17
User entered '1'	System	23 Sep 2020 11:48:04

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:52:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:21:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '18/Nov/2020 14:33'	(b) (4) System	18 Nov 2020 19:33:46

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:52:01

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)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:21:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:45:30
User entered '1'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:46