

US3522297 (Prod: Henry Ford Health System)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:33:39

All time stamps listed in this document are displayed in GMT

US3522297

Form: Participant Creation

Generated On: 26 Nov 2020 09:33:39

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:33:39

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:39

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

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:39

Date of Informed Consent (<i>dd MMM yyyy</i>)	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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:33:39

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:33:39

Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

Were vital signs assessed?	Yes ☒
	No ☐
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 ☐
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 09:33:39

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

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

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Folder: Screening

Form: Risk of Exposure

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:33:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 14:45
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 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: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	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 ☐ Axillary ☐ Other ☒
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

Generated On: 26 Nov 2020 09:33:39

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	21 AUG 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:39

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:39

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 19:28

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: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:39

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.

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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.**

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Yes ☐	
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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Yes ☐	
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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Yes ☐	
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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Yes ☐	
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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Yes ☐	
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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Yes ☐	
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

Generated On: 26 Nov 2020 09:33:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

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

US3522297

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522297

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

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

If Contact Not Made, please provide Comments

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

US3522297

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522297

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

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

US3522297

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522297

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:33:39

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)

Generated On: 26 Nov 2020 09:33:39

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: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522297

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522297

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522297

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522297

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

Were vital signs assessed?	Yes ☐
	No ☒
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 ☐
	Axillary ☐
	Other ☐
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	
Height (derived)	
Weight (derived)	

US3522297

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

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: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2020 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2020 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2020 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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 ☒ 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 ☒
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: 26 Nov 2020 09:33:39

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 ☐ 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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 138

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

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

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

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

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

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

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01

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21 JAN 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01

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28 JAN 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:33:39

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

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11 FEB 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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18 FEB 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 187

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2021 00:01

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25 FEB 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01

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18 MAR 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:33:39

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

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

Date and time of submission

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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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:33:39

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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06 JAN 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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13 JAN 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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

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

Date and time of submission

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16 JAN 2022 00:01

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20 JAN 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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

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

Date and time of submission

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23 JAN 2022 00:01

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27 JAN 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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

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

Date and time of submission

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30 JAN 2022 00:01

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03 FEB 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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

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

Date and time of submission

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10 FEB 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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

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

Date and time of submission

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17 FEB 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

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

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

Date and time of submission

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24 FEB 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

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

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

Date and time of submission

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03 MAR 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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

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

Date and time of submission

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06 MAR 2022 00:01

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10 MAR 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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17 MAR 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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24 MAR 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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31 MAR 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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07 APR 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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

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: 26 Nov 2020 09:33:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

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28 APR 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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02 JUN 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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16 JUN 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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30 JUN 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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14 JUL 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

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21 JUL 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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

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

Date and time of submission

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24 JUL 2022 00:01

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28 JUL 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

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

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

Date and time of submission

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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: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

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

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

Date and time of submission

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07 AUG 2022 00:01

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11 AUG 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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18 AUG 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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

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

Date and time of submission

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21 AUG 2022 00:01

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25 AUG 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

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

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

Date and time of submission

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01 SEP 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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

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

Date and time of submission

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08 SEP 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

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

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

Date and time of submission

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11 SEP 2022 00:01

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15 SEP 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:33:39

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

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

Date and time of submission

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18 SEP 2022 00:01

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22 SEP 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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29 SEP 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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06 OCT 2022 23:59

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

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

If Contact Not Made, please provide Comments

NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS. 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

Generated On: 26 Nov 2020 09:33:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522297

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

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 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:39

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:33:39

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 ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☒
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	298 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
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	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	302 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
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	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	306 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	21 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	310 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
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	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	314 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
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	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	318 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	24 SEP 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	322 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

	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 (8)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	25 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	326 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:33:39

	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 (9)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	26 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
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	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	330 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☒
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	27 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	334 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☒
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	28 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	338 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☒
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	29 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	342 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☒
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	30 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	346 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☒
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
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	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	350 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☒
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	2 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.2 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	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	354 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☒
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	3 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	358 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☒
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	4 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	362 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☒
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	05 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	96.6 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	366 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☒
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	6 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	370 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☒
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	07 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	374 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:33:39

	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)

Generated On: 26 Nov 2020 09:33:39

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☒
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:33:39

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	08 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	378 of 2038	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:33:39

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:33:39

	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

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

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 _____

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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:33:39

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date _____

End Date _____

Non-Invasive Ventilation? Yes ☐
No ☒

Start Date _____

End Date _____

Mechanical Ventilation? Yes ☐
No ☐

Start Date _____

End Date _____

ECMO? Yes ☐
No ☐

Start Date _____

End Date _____

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☒

Start Date _____

End Date _____

Evidence of Shock Requires Vasopressors Yes ☐
No ☐

Start Date _____

End Date _____

Acute Renal Dysfunction? Yes ☐
No ☐

Start Date _____

Hepatic Dysfunction? Yes ☐
No ☐

Start Date _____

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:33:39

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	NA (COVID-19 Negative)	

US3522297

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:33:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD28

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 08:15
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	97.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 OCT 2020

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:33:39

[Visit Date](#)

Please check all assessments that apply for this visit

Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	False
Pregnancy Test	False

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

Were vital signs assessed?	Yes ☐
	No ☐
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 ☐
	Axillary ☐
	Other ☐
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	
Height (derived)	
Weight (derived)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:39

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: Unscheduled 18 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:39

Was the sample collected?

Yes ☐

No ☐

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3522297

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:33:39

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)

Generated On: 26 Nov 2020 09:33:39

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 ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:39

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	True
Concomitant Medication	False
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)

Generated On: 26 Nov 2020 09:33:39

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

Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:33:39

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)

Generated On: 26 Nov 2020 09:33:39

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 ☐ Intraocular ☐

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:39

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
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)

Generated On: 26 Nov 2020 09:33:39

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 ☐ Intraocular ☐

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:39

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 26 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3522297

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:33:39

[Were any concomitant procedures performed?](#)

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3522297

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

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

Generated On: 26 Nov 2020 09:33:39

SAEID	USA-US131-2020-MRNA-1273-P301000004
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:33:39

SAEID	USA-US131-2020-MRNA-1273-P301000004
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	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)

Generated On: 26 Nov 2020 09:33:39

SAEID	USA-US131-2020-MRNA-1273-P301000004
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	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)

Generated On: 26 Nov 2020 09:33:39

SAEID	USA-US131-2020-MRNA-1273-P301000004
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	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)

Generated On: 26 Nov 2020 09:33:39

SAEID	USA-US131-2020-MRNA-1273-P301000004
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	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: 26 Nov 2020 09:33:39

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3522297'	RWS_ENDPOINT ENDPOINT (b) (4) 	21 Aug 2020 18:29:36

US3522297

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:33:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:39:16

US3522297

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:33:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	21 Aug 2020 18:29:37

US3522297

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:33:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Aug 2020 18:39:16

US3522297

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:33:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	21 Aug 2020 18:39:16

US3522297

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:39

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1957'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	21 Aug 2020 18:29:38

US3522297

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:39

[Age](#)

Audit	User	Time (GMT)
User entered '63'	(b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:39

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '63'	System	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:39

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	(b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:39

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Unknown (UNKNOWN)'	(b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:39

[White](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:39

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:39

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:39

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:39

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:39

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:39

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:39:36

US3522297

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:39

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:39

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:39

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
User entered '2020'	System	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:39

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:39

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:39

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:40:16

US3522297

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	21 Aug 2020 18:29:37

US3522297

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:40:33

US3522297

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:33:39

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:40:33

US3522297

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:33:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:40:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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) (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)	05 Nov 2020 14:36:07
User entered '14:45' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 14:36:02
User entered '14:38' reason for change: Data Entry Error	Sharon Mathys (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: 26 Nov 2020 09:33:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '70' in	(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: 26 Nov 2020 09:33:39

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '215' lb	(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: 26 Nov 2020 09:33:39

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 18:41:38

US3522297

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:41:48

US3522297

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 18:41:48

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:39

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:39

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:39

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:39

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:39

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:39

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:39

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:39

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:39

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:39

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:42:14

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No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:39

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:39

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:39

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:39

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:39

Other

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:39

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:42:14

US3522297

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:33:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:42:43

US3522297

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:33:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 18:42:43

US3522297

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:33:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Aug 2020 18:42:43

US3522297

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:33:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	21 Aug 2020 18:42:43

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	21 Aug 2020 18:45:17

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:39

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
User entered '107148'	RWS_ENDPOINT ENDPOINT (b) (4) 	21 Aug 2020 18:45:17

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:39

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) 	21 Aug 2020 18:45:17

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:39

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:42:53

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:39

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:42:53

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:39

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:42:53

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:39

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:42:53

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:39

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:42:53

US3522297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:39

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4)	05 Oct 2020 11:48:20
Amendment Manager: DataPoint set to visible.	(b) (4)	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: 26 Nov 2020 09:33:39

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:39

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:39

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:39

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:45' reason for change: New Information	(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: 26 Nov 2020 09:33:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Temporal' reason for change: Data Entry Error	Sharon Mathys (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: 26 Nov 2020 09:33:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63'	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '15'	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '103'	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '72'	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:39

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:39

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 18:47:39

US3522297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:39

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(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: 26 Nov 2020 09:33:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Aug 2020' reason for change: Data Entry Error	(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: 26 Nov 2020 09:33:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:20' reason for change: Data Entry Error	(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: 26 Nov 2020 09:33:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '97.9' F reason for change: Data Entry Error	(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: 26 Nov 2020 09:33:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)' reason for change: Data Entry Error	(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: 26 Nov 2020 09:33:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Temporal' reason for change: Data Entry Error	(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: 26 Nov 2020 09:33:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60' reason for change: Data Entry Error	(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: 26 Nov 2020 09:33:39

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '15' reason for change: Data Entry Error	(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: 26 Nov 2020 09:33:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116' reason for change: Data Entry Error	(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: 26 Nov 2020 09:33:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '72' reason for change: Data Entry Error	(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: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (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: 26 Nov 2020 09:33:39

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Sharon Mathys (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: 26 Nov 2020 09:33:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:39

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:39

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:50'	(b) (4), (b) (6)	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 15:50'	System	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:39

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 19:54:01

US3522297

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 19:03:59

US3522297

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:39

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 19:03:59

US3522297

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:55' reason for change: Data Entry Error	(b) (4), (b) (6)	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: 26 Nov 2020 09:33:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 19:04:14

US3522297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:33:39

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 19:04:14

US3522297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:33:39

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '14:57' reason for change: Data Entry Error	(b) (4), (b) (6)	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: 26 Nov 2020 09:33:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 19:04:14

US3522297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:33:39

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 19:04:14

US3522297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:33:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 19:04:14

US3522297

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:33:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:47:52

US3522297

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:33:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:47:52

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	21 Aug 2020 20:16:30
User entered 'Yes (Y)'	System	21 Aug 2020 20:16:30

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	21 Aug 2020 20:16:30
User entered '97.9'	System	21 Aug 2020 20:16:30

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	21 Aug 2020 20:16:30
User entered '21 Aug 2020 16:16'	System	21 Aug 2020 20:16:30

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	22 Aug 2020 12:56:21
User entered 'Yes (Y)'	System	22 Aug 2020 12:56:21

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	22 Aug 2020 12:56:21
User entered '97.2'	System	22 Aug 2020 12:56:21

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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'	System	22 Aug 2020 12:56:21
User entered 'Yes (Y)'	System	22 Aug 2020 12:56:21

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with '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'	System	22 Aug 2020 12:56:21
User entered '1'	System	22 Aug 2020 12:56:21

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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'	System	22 Aug 2020 12:56:21
User entered '0'	System	22 Aug 2020 12:56:21

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	22 Aug 2020 12:56:21
User entered '22 Aug 2020 08:56'	System	22 Aug 2020 12:56:21

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:33:39

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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'	System	23 Aug 2020 13:27:30
User entered '97.4'	System	23 Aug 2020 13:27:30

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with '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). 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: 26 Nov 2020 09:33:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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 '0'	System	23 Aug 2020 13:27:30

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	23 Aug 2020 13:27:30
User entered '23 Aug 2020 09:27'	System	23 Aug 2020 13:27:30

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	23 Aug 2020 20:48:38
User entered 'Yes (Y)'	System	23 Aug 2020 20:48:38

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	23 Aug 2020 20:48:38
User entered '98.6'	System	23 Aug 2020 20:48:38

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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'	System	23 Aug 2020 20:48:38
User entered 'No (N)'	System	23 Aug 2020 20:48:38

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	23 Aug 2020 20:48:38
User entered '23 Aug 2020 16:48'	System	23 Aug 2020 20:48:38

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	25 Aug 2020 03:44:26
User entered 'Yes (Y)'	System	25 Aug 2020 03:44:26

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:39

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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'	System	25 Aug 2020 03:44:26
User entered '97.3'	System	25 Aug 2020 03:44:26

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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'	System	25 Aug 2020 03:44:26
User entered 'No (N)'	System	25 Aug 2020 03:44:26

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	25 Aug 2020 03:44:26
User entered '24 Aug 2020 23:44'	System	25 Aug 2020 03:44:26

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	26 Aug 2020 01:32:49
User entered 'Yes (Y)'	System	26 Aug 2020 01:32:49

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:39

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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'	System	26 Aug 2020 01:32:49
User entered '97.0'	System	26 Aug 2020 01:32:49

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	26 Aug 2020 01:32:49
User entered '25 Aug 2020 21:32'	System	26 Aug 2020 01:32:49

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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-55e4bffbfbfc'	System	26 Aug 2020 23:28:56
User entered 'Yes (Y)'	System	26 Aug 2020 23:28:56

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:39

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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-55e4bffbfbfc'	System	26 Aug 2020 23:28:56
User entered '97.5'	System	26 Aug 2020 23:28:56

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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-55e4bffbfbfc'	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: 26 Nov 2020 09:33:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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-55e4bffbfbfc'	System	26 Aug 2020 23:28:56
User entered '26 Aug 2020 19:28'	System	26 Aug 2020 23:28:56

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	28 Aug 2020 12:26:09
User entered 'Yes (Y)'	System	28 Aug 2020 12:26:09

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	28 Aug 2020 12:26:09
User entered '97.8'	System	28 Aug 2020 12:26:09

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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'	System	28 Aug 2020 12:26:09
User entered 'No (N)'	System	28 Aug 2020 12:26:09

US3522297

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-22T08:57:09', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '30715b11-8066-4ee5-b3ef-2466e0bcecebe'	System	22 Aug 2020 12:58:36
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 12:58:36

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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-2466e0bcecebe'	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: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:33:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:33:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[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)
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: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[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)
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'	System	23 Aug 2020 13:29:37
User entered '1'	System	23 Aug 2020 13:29:37

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:39

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:33:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	23 Aug 2020 13:29:37
User entered '23 Aug 2020 09:29'	System	23 Aug 2020 13:29:37

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:33:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	23 Aug 2020 20:49:42
User entered '23 Aug 2020 16:49'	System	23 Aug 2020 20:49:42

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:33:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:33:16', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '36349a12-95b5-48a2-a3be-fc4ac1b69e3b'	System	26 Aug 2020 01:34:03
User entered 'None (1)'	System	26 Aug 2020 01:34:03

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	26 Aug 2020 01:34:03
User entered 'No (N)'	System	26 Aug 2020 01:34:03

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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'	System	26 Aug 2020 01:34:03
User entered 'No (N)'	System	26 Aug 2020 01:34:03

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:39

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:33:47', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '36349a12-95b5-48a2-a3be-fc4ac1b69e3b'	System	26 Aug 2020 01:34:03
User entered 'None (1)'	System	26 Aug 2020 01:34:03

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-26T19:28:57', 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: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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'	System	26 Aug 2020 23:29:12
User entered 'No (N)'	System	26 Aug 2020 23:29:12

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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'	System	26 Aug 2020 23:29:12
User entered 'No (N)'	System	26 Aug 2020 23:29:12

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:39

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:33:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	26 Aug 2020 23:29:12
User entered '26 Aug 2020 19:29'	System	26 Aug 2020 23:29:12

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:33:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:33:39

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:33:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	28 Aug 2020 12:25:46
User entered '28 Aug 2020 08:25'	System	28 Aug 2020 12:25:46

US3522297

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	22 Aug 2020 12:59:38
User entered 'None (0)'	System	22 Aug 2020 12:59:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:39

CHILLS

Audit	User	Time (GMT)
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'	System	22 Aug 2020 12:59:38
User entered 'None (0)'	System	22 Aug 2020 12:59:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:33:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	22 Aug 2020 12:59:38
User entered '22 Aug 2020 08:59'	System	22 Aug 2020 12:59:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

HEADACHE

Audit	User	Time (GMT)
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'	System	23 Aug 2020 13:30:27
User entered 'No interference with activity (1)'	System	23 Aug 2020 13:30:27

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:39

FATIGUE

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:33:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:33:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	23 Aug 2020 13:30:27
User entered 'None (0)'	System	23 Aug 2020 13:30:27

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:39

CHILLS

Audit	User	Time (GMT)
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'	System	23 Aug 2020 13:30:27
User entered 'None (0)'	System	23 Aug 2020 13:30:27

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T09:30:20', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8b35d93d-4e11-4c77-b349-fe1d98567f7e'	System	23 Aug 2020 13:30:27
User entered 'No (N)'	System	23 Aug 2020 13:30:27

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	23 Aug 2020 13:30:27
User entered '23 Aug 2020 09:30'	System	23 Aug 2020 13:30:27

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

HEADACHE

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:33:39

FATIGUE

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:33:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:33:39

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-23T16:50:14', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '95ca0d50-78bc-4ffd-be13-e23e0b7f4c70'	System	23 Aug 2020 20:50:22
User entered 'No (N)'	System	23 Aug 2020 20:50:22

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	23 Aug 2020 20:50:22
User entered '23 Aug 2020 16:50'	System	23 Aug 2020 20:50:22

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

FATIGUE

Audit	User	Time (GMT)
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'	System	25 Aug 2020 03:45:25
User entered 'None (0)'	System	25 Aug 2020 03:45:25

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	25 Aug 2020 03:45:25
User entered 'No interference with activity (1)'	System	25 Aug 2020 03:45:25

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	25 Aug 2020 03:45:25
User entered 'No interference with activity (1)'	System	25 Aug 2020 03:45:25

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	25 Aug 2020 03:45:25
User entered 'None (0)'	System	25 Aug 2020 03:45:25

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:39

CHILLS

Audit	User	Time (GMT)
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'	System	25 Aug 2020 03:45:25
User entered 'None (0)'	System	25 Aug 2020 03:45:25

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-24T23:45:20', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '597a8a3e-b9aa-41e6-9583-8d4ca6dad6bf'	System	25 Aug 2020 03:45:25
User entered 'No (N)'	System	25 Aug 2020 03:45:25

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

HEADACHE

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:33:39

FATIGUE

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:33:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:33:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:33:39

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1600802B-58A6-4FB6-A07A-93A03AC24AE8)', Time: '2020-08-25T21:34:29', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: 'f1c13421-f1d3-48aa-a6e5-73aa4d383040'	System	26 Aug 2020 01:34:36
User entered 'No (N)'	System	26 Aug 2020 01:34:36

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	26 Aug 2020 01:34:36
User entered '25 Aug 2020 21:34'	System	26 Aug 2020 01:34:36

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

HEADACHE

Audit	User	Time (GMT)
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'	System	26 Aug 2020 23:29:38
User entered 'None (0)'	System	26 Aug 2020 23:29:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:39

FATIGUE

Audit	User	Time (GMT)
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'	System	26 Aug 2020 23:29:38
User entered 'None (0)'	System	26 Aug 2020 23:29:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	26 Aug 2020 23:29:38
User entered 'None (0)'	System	26 Aug 2020 23:29:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	26 Aug 2020 23:29:38
User entered 'None (0)'	System	26 Aug 2020 23:29:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	26 Aug 2020 23:29:38
User entered 'None (0)'	System	26 Aug 2020 23:29:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:39

CHILLS

Audit	User	Time (GMT)
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'	System	26 Aug 2020 23:29:38
User entered 'None (0)'	System	26 Aug 2020 23:29:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:33:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	26 Aug 2020 23:29:38
User entered '26 Aug 2020 19:29'	System	26 Aug 2020 23:29:38

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

FATIGUE

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:33:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:33:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:33:39

CHILLS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:33:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	28 Aug 2020 12:26:30
User entered '28 Aug 2020 08:26'	System	28 Aug 2020 12:26:30

US3522297

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 14:32:47

US3522297

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 14:32:47

US3522297

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 14:32:47

US3522297

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 09:33:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 14:32:51

US3522297

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 14:32:51

US3522297

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020' reason for change: Per Query Resolution	Sharon Mathys (b) (4)	10 Nov 2020 17:54:00
User entered '4 Sep 2020'	Tyler Prentiss (b) (4)	04 Sep 2020 17:42:41

US3522297

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tyler Prentiss (b) (4) (b) (4)	04 Sep 2020 17:42:41

US3522297

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure.'	Tyler Prentiss (b) (4) (b) (4)	04 Sep 2020 17:42:41

US3522297

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	04 Sep 2020 17:44:03

US3522297

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 17:44:03

US3522297

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 14:59:50

US3522297

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 14:59:50

US3522297

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Sep 2020 14:59:50

US3522297

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 09:33:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 18:01:01

US3522297

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:33:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM : Please provide the data for the Vital signs-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), (b) (6)	06 Nov 2020 12:55:14
User entered 'No (N)'	Sharon Mathys (b) (4)	05 Oct 2020 19:59:02

US3522297

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:33:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	05 Oct 2020 19:59:02

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:39

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:39

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:27:20

US3522297

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
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) (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)	
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 13:46:01
	Sharon Mathys (b) (4)	09 Oct 2020 18:52:57
	(b) (4)	

US3522297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:33:39

[If No, reason not given](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 18:52:57

US3522297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:33:39

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 18:52:57

US3522297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:33:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 18:52:57

US3522297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:33:39

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 18:52:57

US3522297

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:27:29

US3522297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:33:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
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 (2)

Generated On: 26 Nov 2020 09:33:39

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
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 (2)

Generated On: 26 Nov 2020 09:33:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:27:35

US3522297

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 19:59:07

US3522297

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	09 Oct 2020 19:09:51
User entered 'No (N)'	Sharon Mathys (b) (4)	09 Oct 2020 18:53:41

US3522297

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	09 Oct 2020 19:09:51
User entered empty.	Sharon Mathys (b) (4)	09 Oct 2020 18:53:41

US3522297

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sharon Mathys (b) (4)	09 Oct 2020 19:09:51
reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	09 Oct 2020 18:53:41
	(b) (4)	

US3522297

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Taken over by daily telemedicine illness visits.'	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 18:53:41

US3522297

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 18:53:48

US3522297

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	09 Oct 2020 19:10:06
User entered 'No (N)'	Sharon Mathys (b) (4)	09 Oct 2020 18:54:14

US3522297

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	09 Oct 2020 19:10:06
User entered empty.	Sharon Mathys (b) (4)	09 Oct 2020 18:54:14

US3522297

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sharon Mathys (b) (4)	09 Oct 2020 19:10:06
reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	09 Oct 2020 18:54:14
	(b) (4)	

US3522297

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'TAKEN OVER BY DAILY TELEMEDICINE ILLNESS VISITS with Study physician'	Sharon Mathys (b) (4) (b) (4)	09 Oct 2020 18:54:14

US3522297

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 18:56:46

US3522297

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Eis (b) (4) [REDACTED]	09 Oct 2020 18:57:55

US3522297

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) [REDACTED]	09 Oct 2020 18:57:55

US3522297

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) [REDACTED]	09 Oct 2020 18:57:55

US3522297

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:10:18

US3522297

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:33:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
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) (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)	19 Oct 2020 14:20:25

US3522297

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:33:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	19 Oct 2020 14:20:25

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:55:38

US3522297

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 18:55:53

US3522297

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:39

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 18:55:53

US3522297

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 18:55:53

US3522297

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:55:53

US3522297

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 14:20:31

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[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: '2020-10-21T18:54:33', 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: 26 Nov 2020 09:33:39

Have you been exposed to someone with 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: '2020-10-21T18:54:28', 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: 26 Nov 2020 09:33:39

[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: '2020-10-21T18:54:49', 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: 26 Nov 2020 09:33:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

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: '2020-10-30T12:31:04', 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: 26 Nov 2020 09:33:39

Have you been exposed to someone with 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: '2020-10-30T12:31:30', 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: 26 Nov 2020 09:33:39

[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: '2020-10-30T12:32:08', 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: 26 Nov 2020 09:33:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

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: '2020-11-04T06:46:38', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8eb738f8-8924-499f-b69d-334500aaef2d'	System	04 Nov 2020 11:50:32
User entered 'No (N)'	System	04 Nov 2020 11:50:32

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

Have you been exposed to someone with 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: '2020-11-04T06:46:48', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8eb738f8-8924-499f-b69d-334500aaef2d'	System	04 Nov 2020 11:50:32
User entered 'No (N)'	System	04 Nov 2020 11:50:32

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

[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: '2020-11-04T06:50:29', User OID: 'PatientReportedOutcome (US3522297)', ODM File OID: '8eb738f8-8924-499f-b69d-334500aaef2d'	System	04 Nov 2020 11:50:32
User entered '04 Nov 2020 06:50:29'	System	04 Nov 2020 11:50:32

US3522297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

[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 Oct 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: 26 Nov 2020 09:33:39

[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 Oct 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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

[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 Oct 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: 26 Nov 2020 09:33:39

[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 Oct 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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

[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 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: 26 Nov 2020 09:33:39

[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 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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

[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 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: 26 Nov 2020 09:33:39

[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 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: 26 Nov 2020 09:33:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:54:02
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 00:54:02

US3522297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:39

[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 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: 26 Nov 2020 09:33:39

[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 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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

Have you been exposed to someone with 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' User entered 'Yes (Y)'	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: 26 Nov 2020 09:33:39

[Please 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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 15:16:46

US3522297

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 15:16:46

US3522297

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Nov 2020 15:16:46

US3522297

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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) (6)	13 Nov 2020 15:16:46

US3522297

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 15:16:06

US3522297

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 15:16:06

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:33:39

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)'	Sharon Mathys (b) (4)	18 Sep 2020 12:18:37

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

Date

Audit	User	Time (GMT)
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'.	Sharon Mathys (b) (4)	10 Nov 2020 18:17:39
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)	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)	10 Nov 2020 18:15:26
User entered '17 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (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)	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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)	10 Nov 2020 18:14:51
User entered '0'	Sharon Mathys (b) (4)	22 Sep 2020 11:29:19
	(b) (4)	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 18:14:51
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 18:14:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:12:18
User entered '98'	Sharon Mathys (b) (4)	22 Sep 2020 11:29:19
	(b) (4)	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Sep 2020 11:29:19

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Date](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Sep 2020 11:29:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	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: 26 Nov 2020 09:33:39

[Date](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Sep 2020 11:30:16

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	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: 26 Nov 2020 09:33:39

[Date](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Sep 2020 18:09:59

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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 (5)

Generated On: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	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: 26 Nov 2020 09:33:39

[Date](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Sep 2020 18:11:06

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:16:03
User entered 'None (None)'	Sharon Mathys (b) (4)	24 Sep 2020 18:11:06

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	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: 26 Nov 2020 09:33:39

[Date](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Sep 2020 18:11:50

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	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: 26 Nov 2020 09:33:39

[Date](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Sep 2020 18:13:00

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	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: 26 Nov 2020 09:33:39

[Date](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 11:53:27

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:33:39

[Date](#)

Audit	User	Time (GMT)
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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Oct 2020 11:53:27

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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 (10)

Generated On: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	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: 26 Nov 2020 09:33:39

[Date](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Oct 2020 11:54:10

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:19:33
User entered 'None (None)'	Sharon Mathys (b) (4)	05 Oct 2020 11:54:10
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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 (11)

Generated On: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	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: 26 Nov 2020 09:33:39

[Date](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Oct 2020 11:54:43

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:03
User entered 'None (None)'	Sharon Mathys (b) (4)	05 Oct 2020 11:54:43
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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 (12)

Generated On: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	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: 26 Nov 2020 09:33:39

[Date](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Oct 2020 14:13:14

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	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: 26 Nov 2020 09:33:39

[Date](#)

Audit	User	Time (GMT)
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)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Oct 2020 14:17:45

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Form: Symptom Log (13)

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[Temperature](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:43
User entered 'None (None)'	Sharon Mathys (b) (4)	05 Oct 2020 14:17:45
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:18:29

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Form: Symptom Log (14)

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[Date](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Oct 2020 14:18:29

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:20:53
User entered 'None (None)'	Sharon Mathys (b) (4)	05 Oct 2020 14:18:29
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:19:25

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Form: Symptom Log (15)

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[Date](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (15)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Oct 2020 14:19:25

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Form: Symptom Log (15)

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[Temperature](#)

Audit	User	Time (GMT)
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

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:09
User entered 'None (None)'	Sharon Mathys (b) (4)	05 Oct 2020 14:19:25
	(b) (4)	

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)'	Sharon Mathys (b) (4) (b) (4)	05 Oct 2020 14:20:08

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:33:39

[Date](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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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Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4)	05 Oct 2020 14:20:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4)	05 Oct 2020 14:20:08
	(b) (4)	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4)	05 Oct 2020 14:20:08
	(b) (4)	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4)	05 Oct 2020 14:20:08

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:16
User entered 'None (None)'	Sharon Mathys (b) (4)	05 Oct 2020 14:20:08
	(b) (4)	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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 (17)

Generated On: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 17 (Day 17)'	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: 26 Nov 2020 09:33:39

[Date](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered '0'	Sharon Mathys (b) (4)	05 Oct 2020 14:21:08
	(b) (4)	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Oct 2020 14:21:08

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4)	05 Oct 2020 14:21:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4)	05 Oct 2020 14:21:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4)	05 Oct 2020 14:21:08
	(b) (4)	

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Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4)	05 Oct 2020 14:21:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4)	05 Oct 2020 14:21:08
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:25
User entered 'None (None)'	Sharon Mathys (b) (4)	05 Oct 2020 14:21:08
	(b) (4)	

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Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 18 (Day 18)'	Sharon Mathys (b) (4) (b) (4)	19 Oct 2020 14:28:28

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Form: Symptom Log (18)

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[Date](#)

Audit	User	Time (GMT)
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

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Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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

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Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Oct 2020 14:28:28

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Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:21:54
User entered 'None (None)'	Sharon Mathys (b) (4)	19 Oct 2020 14:28:28
	(b) (4)	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 19 (Day 19)'	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: 26 Nov 2020 09:33:39

[Date](#)

Audit	User	Time (GMT)
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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Oct 2020 14:29:53

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:01
User entered 'None (None)'	Sharon Mathys (b) (4)	19 Oct 2020 14:29:53
	(b) (4)	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 20 (Day 20)'	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: 26 Nov 2020 09:33:39

[Date](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Oct 2020 14:31:16

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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 (21)

Generated On: 26 Nov 2020 09:33:39

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 21 (Day 21)'	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: 26 Nov 2020 09:33:39

[Date](#)

Audit	User	Time (GMT)
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)	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)	19 Oct 2020 14:31:57

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:33:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[O2 Saturation](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:33:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Oct 2020 14:31:57

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:33:39

[Temperature](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:26
User entered 'None (None)'	Sharon Mathys (b) (4)	19 Oct 2020 14:31:57
	(b) (4)	

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:33:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Headache](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Diarrhea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Sore Throat](#)

Audit	User	Time (GMT)
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: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:33:39

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:33:39

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:33:39

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	22 Sep 2020 11:28:09

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Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:33:39

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:33:39

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:33:39

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:33:39

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:33:39

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:33:39

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:33:39

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 11:28:09

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:33:39

Did the subject have Respiratory Rates $\geq$ 30 per Minute?

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:33:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:33:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

Did the subject have Oxygen Saturation of SpO2 $\leq$ 93% on room air at sea level?

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:33:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:33:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:33:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:33:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:33:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
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

US3522297

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:33:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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[Clinical Evidence](#)

Audit	User	Time (GMT)
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

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[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Radiographical Evidence](#)

Audit	User	Time (GMT)
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

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[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:33:39

[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

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:33:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:33:39

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:33:39

[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

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:33:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	22 Sep 2020 11:35:47

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:33:39

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	24 Sep 2020 18:13:30
User entered empty.	Sharon Mathys (b) (4)	22 Sep 2020 11:35:47

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	22 Sep 2020 11:35:47

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:33:39

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	24 Sep 2020 18:13:30
User entered empty.	Sharon Mathys (b) (4)	22 Sep 2020 11:35:47

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:33:39

[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

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:33:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:30:06
User entered 'Yes (Y)' reason for change: New Information	Sharon Mathys (b) (4)	05 Oct 2020 11:56:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Please leave blank until we fill in' (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)	26 Sep 2020 20:42:38
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	22 Sep 2020 11:35:47
	Sharon Mathys (b) (4)	22 Sep 2020 11:35:47
	(b) (4)	

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:33:39

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:30:06
User entered '26 Sep 2020' reason for change: New Information	Sharon Mathys (b) (4)	05 Oct 2020 11:56:25
User entered empty.	Sharon Mathys (b) (4)	22 Sep 2020 11:35:47

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:33:39

[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

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:33:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:33:39

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:30:06
User entered '1 Oct 2020' reason for change: New Information	Sharon Mathys (b) (4)	05 Oct 2020 14:12:10
User entered empty.	Sharon Mathys (b) (4)	22 Sep 2020 11:35:47

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 09:33:39

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	29 Oct 2020 12:25:18
User entered empty.	Sharon Mathys (b) (4)	22 Sep 2020 11:35:47

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	
Query 'Data is required. Please complete.' answered with 'Please leave blank until we fill in' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 07:37:04
User opened query 'Data is required. Please complete.' (Site from System).	Sharon Mathys (b) (4)	26 Sep 2020 20:43:09
User entered empty.	(b) (4)	
	System	22 Sep 2020 11:35:47
	Sharon Mathys (b) (4)	22 Sep 2020 11:35:47
	(b) (4)	

US3522297

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:33:39

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	22 Sep 2020 11:28:24

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

Height (xxx.x)

Audit	User	Time (GMT)
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)	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: 26 Nov 2020 09:33:39

Weight (xxx.x)

Audit	User	Time (GMT)
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)	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: 26 Nov 2020 09:33:39

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 18:52:29

US3522297

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	19 Oct 2020 14:19:32

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Oct 2020 14:21:41

US3522297

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: Unscheduled 18 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:33:39

[Visit Date](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 01:49:23
User closed query 'Per CDM: Please consider removing all data from this visit permitting inactivation of forms as it appears to be a duplicate of Illness Visit Day 1' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 01:49:16
Query 'Per CDM: Please consider removing all data from this visit permitting inactivation of forms as it appears to be a duplicate of Illness Visit Day 1' answered with 'removed data' (Site from DM).	Sharon Mathys (b) (4)	10 Nov 2020 14:02:35
Query 'Data is required. Please complete.' answered with 'cleared to inactivate' (Site from System).	(b) (4)	10 Nov 2020 14:02:25
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 14:02:12
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:02:12
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:02:12
User opened query 'Per CDM: Please consider removing all data from this visit permitting inactivation of forms as it appears to be a duplicate of Illness Visit Day 1' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:55:11
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:56:33
User entered '18 Sep 2020'	Sharon Mathys (b) (4)	22 Sep 2020 18:53:58

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:33:39

[Physical Exam](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:02:12
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:02:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:56:33
User entered '1'	Sharon Mathys (b) (4)	22 Sep 2020 18:53:58
	(b) (4)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:33:39

[Vital Signs](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:02:12
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:02:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:56:33
User entered '1'	Sharon Mathys (b) (4)	22 Sep 2020 18:53:58
	(b) (4)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:33:39

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:02:12
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:02:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:56:33
User entered '1'	Sharon Mathys (b) (4)	22 Sep 2020 18:53:58
	(b) (4)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:33:39

[Pregnancy Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:56:33
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:53:58

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 01:49:31
Query 'Data is required. Please complete.' answered with 'cleared for deletion' (Site from System).	Sharon Mathys (b) (4)	10 Nov 2020 14:03:09
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 14:03:03
	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:56:38
User entered 'Yes (Y)'	(b) (4)	
	Sharon Mathys (b) (4)	22 Sep 2020 18:59:07
	(b) (4)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:56:38
User entered '18 Sep 2020'	Sharon Mathys (b) (4)	22 Sep 2020 18:59:07
	(b) (4)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:56:38
User entered '15:50'	Sharon Mathys (b) (4)	22 Sep 2020 18:59:07
	(b) (4)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:03:03
User entered '18 Sep 2020 15:50'	System	22 Sep 2020 18:59:07

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:56:38
User entered '98.1' F	Sharon Mathys (b) (4)	22 Sep 2020 18:59:07
	(b) (4)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:56:38
User entered 'Oral (Oral)'	Sharon Mathys (b) (4)	22 Sep 2020 18:59:07
	(b) (4)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 15:31:06
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:56:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:59:07

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:56:38
User entered '78'	Sharon Mathys (b) (4)	22 Sep 2020 18:59:07
	(b) (4)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:03:03
User entered 'bpm'	System	22 Sep 2020 18:59:07

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:56:38
User entered '16'	Sharon Mathys (b) (4)	22 Sep 2020 18:59:07
	(b) (4)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:03:03
User entered 'breaths/min'	System	22 Sep 2020 18:59:07

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:56:38
User entered '113'	Sharon Mathys (b) (4)	22 Sep 2020 18:59:07
	(b) (4)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:03:03
User entered 'mmHg'	System	22 Sep 2020 18:59:07

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:03:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:56:38
User entered '76'	Sharon Mathys (b) (4)	22 Sep 2020 18:59:07
	(b) (4)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:03:03
User entered 'mmHg'	System	22 Sep 2020 18:59:07

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 01:49:03
Query 'Data is required. Please complete.' answered with 'removed' (Site from System).	Sharon Mathys (b) (4)	10 Nov 2020 17:40:24
Query 'Please remove data from this field' answered with 'removed' (Site from CRA).	(b) (4)	
Query 'Please remove data from this field' answered with 'removed' (Site from CRA).	Sharon Mathys (b) (4)	10 Nov 2020 17:40:21
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 17:40:09
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 17:40:09
User opened query 'Please remove data from this field' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 15:31:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:31:24
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	08 Oct 2020 19:57:35
	(b) (4)	
	Sharon Mathys (b) (4)	22 Sep 2020 18:55:03
	(b) (4)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:39

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 17:40:09
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 15:31:25
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:57:35
User entered '18 Sep 2020'	Sharon Mathys (b) (4)	22 Sep 2020 18:55:03
	(b) (4)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 01:48:55
Query 'Data is required. Please complete.' answered with 'cleared for inactivation' (Site from System).	Sharon Mathys (b) (4)	10 Nov 2020 14:19:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 14:13:10
	Sharon Mathys (b) (4)	10 Nov 2020 14:13:10
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	10 Nov 2020 14:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:58:02
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	22 Sep 2020 18:54:52
	(b) (4)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:39

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:13:10
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:58:02
User entered '18 Sep 2020'	Sharon Mathys (b) (4)	22 Sep 2020 18:54:52
	(b) (4)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:13:10
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:58:02
User entered '16:00'	Sharon Mathys (b) (4)	22 Sep 2020 18:54:52
	(b) (4)	

US3522297

Folder: Unscheduled 18 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:13:10
User entered '18 Sep 2020 16:00'	System	22 Sep 2020 18:54:52

US3522297

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:33:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:35:19
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	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
User coded data point as SOC: Infections and infestations, HLGT: 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

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. Data point term sent to Coder DataPoint Un-verified.	Coder Import (b) (4) (b) (4) System Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 00:04:35 21 Oct 2020 13:33:33 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). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Oct 2020 12:26:17 08 Oct 2020 19:58:55
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 11:56:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	22 Sep 2020 11:56:42 22 Sep 2020 11:35:56
User entered 'Symptomatic 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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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Folder: Adverse Events

Form: Adverse Events (3)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 11:34:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

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Folder: Adverse Events

Form: Adverse Events (3)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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)	17 Nov 2020 13:14:21
DataPoint Un-verified.	(b) (4)	
	Sharon Mathys (b) (4)	17 Nov 2020 13:14:11
User entered '26 Sep 2020' reason for change: Per Query Resolution	(b) (4)	
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
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:38:03

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Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6)	29 Sep 2020 16:56:00
	Sharon Mathys (b) (4)	22 Sep 2020 11:34:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 11:34:03

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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Folder: Adverse Events

Form: Adverse Events (3)

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(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)	21 Oct 2020 13:32:29
DataPoint Un-verified.	Sharon Mathys (b) (4)	21 Oct 2020 13:32:21
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Per Query Resolution	Sharon Mathys (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)

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[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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[None](#)

Audit	User	Time (GMT)
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

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)
DataPoint Verified.	(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)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:35:19
DataPoint Un-verified.	Sharon Mathys (b) (4)	21 Oct 2020 13:36:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Sharon Mathys (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)	22 Sep 2020 11:34:03

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:35:19
DataPoint Un-verified.	Sharon Mathys (b) (4)	21 Oct 2020 13:36:26
User entered empty; reason for change Per Query Resolution	(b) (4)	
	Sharon Mathys (b) (4)	21 Oct 2020 13:36:26
DataPoint Verified.	(b) (4)	
	(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)	22 Sep 2020 11:34:03
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
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) (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
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:58:55

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[Narrative](#)

Audit	User	Time (GMT)
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

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:39

[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

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:39

[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

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	22 Sep 2020 11:34:03

US3522297

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Sep 2020 11:34:03

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:33:39

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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	System	09 Oct 2020 17:26:06
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	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	System	28 Aug 2020 14:35:00
User entered 'Aspirin'	(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: 26 Nov 2020 09:33:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Indication](#)

Audit	User	Time (GMT)
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
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) (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) (b) (4)	30 Oct 2020 17:13:47

US3522297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:39

[Indication](#)

Audit	User	Time (GMT)
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
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)	09 Oct 2020 17:25:28
User entered 'JOINT Aches in Several Joints' reason for change: Data Entry Error	Sharon Mathys (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)	21 Sep 2020 12:45:53
User entered 'Joint pain post injection'	(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: 26 Nov 2020 09:33:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	17 Nov 2020 13:10:56
	(b) (4)	
User entered '23 Aug 2020' reason for change: Per Query Resolution	Sharon Mathys (b) (4)	17 Nov 2020 13:10:56
	(b) (4)	
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: 26 Nov 2020 09:33:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:35:49
User entered 'Yes (Y)'	(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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Indication](#)

Audit	User	Time (GMT)
User entered 'SYMPTOMATIC COVID-19 Infection' reason for change: Data Entry Error	Sharon Mathys (b) (4)	17 Nov 2020 13:14:44
User entered 'Symptomatic Covid-19'	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: 26 Nov 2020 09:33:39

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	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: 26 Nov 2020 09:33:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Sep 2020'	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: 26 Nov 2020 09:33:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 13:11:41

US3522297

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:33:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:48:10

US3522297

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:33:39

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'Due to SARS-COV-2 (COVID)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 11:32:55

US3522297

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:33:39

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:33:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Site Address:](#) City

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Site Address:](#) [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

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)	08 Oct 2020 19:58:19
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:28:36
User entered '1'	(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: 26 Nov 2020 09:33:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Site Address:](#) [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

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)
Reviewed for Safety.	(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: 26 Nov 2020 09:33:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Site Address:](#) [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '05/Nov/2020 22:14'	System	05 Nov 2020 22:14:16

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:33:39

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)
Reviewed for Safety.	(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: 26 Nov 2020 09:33:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Site Address:](#) City

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:33:39

[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: 26 Nov 2020 09:33:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '18/Nov/2020 14:33'	System	18 Nov 2020 19:33:46

US3522297

Folder: SAE USA-US131-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:33:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 19:33:46