

US3522042 (Prod: Henry Ford Health System)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:31:01

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US3522042

Form: Participant Creation

Generated On: 26 Nov 2020 09:31:01

[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 09:31:01

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:01

Date of Birth (MMM yyyy)	(b) (6) 1985
Age	34
Age Units	YEARS
Age (Derived)	34
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:01

Date of Informed Consent (<i>dd MMM yyyy</i>)	07 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☒
	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 09:31:01

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:31:01

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:01

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

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:01

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	07 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:55 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 09:55
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	178.2 lb
BMI (<i>xxx.x</i>)	27.96842 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 09:31:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

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 09:31:01

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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:01

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

What was the participant's randomization number? 101710

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:01

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 09:31:01

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

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

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 7 AUG 2020

What was the treatment time? (00:00-23:59) 10:50 (24 HR)

Treatment Date and Time (derived) 7 AUG 2020 10:50

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

7 AUG 2020

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

09:47 (24 HR)

Collection date and time (derived)

7 AUG 2020 09:47

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:31:01

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

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐
No ☒

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

PC Time Stamp 07 AUG 2020 11:20

PC Open Date & Time 07 AUG 2020 11:20

PC Close Date & Time 07 AUG 2020 13:50

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 14:50

PC Open Date & Time

07 AUG 2020 14:45

PC Close Date & Time

08 AUG 2020 11:59

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 12:04

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 14:46

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 16:07

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 12:24

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 13:49

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 12:18

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 11:21

PC Open Date & Time

07 AUG 2020 11:20

PC Close Date & Time

07 AUG 2020 13:50

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 14:45

PC Open Date & Time

07 AUG 2020 14:45

PC Close Date & Time

08 AUG 2020 11:59

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 12:00

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 14:45

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 16:07

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 12:22

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 13:50

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 12:18

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 11:21
PC Open Date & Time	07 AUG 2020 11:20
PC Close Date & Time	07 AUG 2020 13:50

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 14:45
PC Open Date & Time	07 AUG 2020 14:45
PC Close Date & Time	08 AUG 2020 11:59

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 AUG 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

ATTEMPTED TO CALL PATIENT,
DID NOT ANSWER; VOICEMAIL
WAS LEFT

If Contact Not Made, please provide Comments

US3522042

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

PT IS GOOD, NO ADVERSE
EVENTS

If Contact Not Made, please provide Comments

US3522042

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3522042

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3522042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

Was this visit performed?	Yes ☐
	No ☒

Visit date (dd MMM yyyy)	

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

Folder OID	VISIT2

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:01

Height	
Weight	

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

Height		
Weight		
Timepoint		Pre-Dose ☒
		Post-Dose ☐
Were vital signs assessed?		Yes ☐
		No ☒
Date of assessment (dd MMM yyyy)		
Time of assessment (00:00-23:59)		
Vital Signs Date and Time (derived)		
Temperature (xxx.x)		
Route of measurement		Oral ☐
		Axillary ☐
		Other ☐
If Other, specify		
Pulse (xxx)		
Pulse units		
Respiratory Rate (xxx)		
Respiratory Rate units		
Systolic Blood Pressure (xxx)		
Systolic Blood Pressure units		
Diastolic Blood Pressure (xxx)		
Diastolic Blood Pressure units		

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

Height		
Weight		
Timepoint		Pre-Dose ☐
		Post-Dose ☒
Were vital signs assessed?		Yes ☐
		No ☒
Date of assessment (dd MMM yyyy)		
Time of assessment (00:00-23:59)		
Vital Signs Date and Time (derived)		
Temperature (xxx.x)		
Route of measurement		Oral ☐
		Axillary ☐
		Other ☐
If Other, specify		
Pulse (xxx)		
Pulse units		
Respiratory Rate (xxx)		
Respiratory Rate units		
Systolic Blood Pressure (xxx)		
Systolic Blood Pressure units		
Diastolic Blood Pressure (xxx)		
Diastolic Blood Pressure units		

US3522042

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3522042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3522042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3522042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:31:01

Collection date (*dd MMM yyyy*)

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

US3522042

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3522042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

PATIENT WAS COVID-POSITIVE;
PHYSICIAN DR. RAMESH WAS
PERFORMING ACTIVE
TELEMEDICINE AND ILLNESS
VISITS IN LIEU OF SAFETY
PHONE CALLS

US3522042

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

PATIENT WAS COVID-POSITIVE;
PHYSICIAN DR. RAMESH WAS
PERFORMING ACTIVE
TELEMEDICINE AND ILLNESS
VISITS IN LIEU OF SAFETY
PHONE CALLS

US3522042

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

PATIENT WAS COVID POSITIVE,
DID NOT RECEIVE SECOND
DOSAGE HAS BEEN DOING
ILLNESS VISITS WITH STUDY
DOCTOR.

US3522042

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 OCT 2020

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

US3522042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 OCT 2020 06:30:58

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 05:32:02

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 07:43:06

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2020 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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°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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2020 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2020 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2020 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 103

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2020 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 159

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

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

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

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2021 00:01

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14 JAN 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

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21 JAN 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 208

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 355

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

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

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

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

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

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

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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 369

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

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

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

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

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

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

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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 383

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

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

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

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

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

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

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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 488

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

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

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

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

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

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

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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 509

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

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

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

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

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

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

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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

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06 JAN 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 523

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

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

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

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

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

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

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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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13 JAN 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

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20 JAN 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 537

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

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

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

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

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

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

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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

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27 JAN 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

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30 JAN 2022 00:01

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03 FEB 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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10 FEB 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 558

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

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

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

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

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

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

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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 565

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

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

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

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

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

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

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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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24 FEB 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

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27 FEB 2022 00:01

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03 MAR 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

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06 MAR 2022 00:01

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10 MAR 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 586

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 593

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

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

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

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

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

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

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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 698

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

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

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

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

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

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

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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

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14 JUL 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3522042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LEFT A VOICEMAIL

If Contact Not Made, please provide Comments

US3522042

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	22 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	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)	303 of 2112	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

	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	☐

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

Symptom Day

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	25 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	307 of 2112	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

	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	☐

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

Symptom Day

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	26 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	311 of 2112	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

	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	☐

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	27 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	315 of 2112	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

	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	☐

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

Symptom Day

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	28 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	319 of 2112	

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

	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	☐

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	29 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	323 of 2112	

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

	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	☐

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	30 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	327 of 2112	

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

	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	☐

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

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

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	31 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	331 of 2112	

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

	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	☐

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

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

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

Symptom Day

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

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	1 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	335 of 2112	

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

	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	☐

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

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

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

Symptom Day

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

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	2 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	339 of 2112	

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

	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	☐

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

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

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

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

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	3 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	343 of 2112	

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

	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	☐

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

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

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

Symptom Day

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	4 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	347 of 2112	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

	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	☐

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

Symptom Day

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	5 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	351 of 2112	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

	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	☐

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

Symptom Day

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	6 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	355 of 2112	

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

	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	☐

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

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

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

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

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	7 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	359 of 2112	

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

	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	☐

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

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

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

Symptom Day

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

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	08 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	363 of 2112	

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

	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	☐

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	09 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	367 of 2112	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

	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	☐

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

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

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	10 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Cough	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Shortness of Breath	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Difficulty Breathing	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Fatigue	None ☒	
v6.020 DTW (1102)	371 of 2112	

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

	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	☐

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	375 of 2112	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

	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	☐

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

Symptom Day

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	12 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Cough	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Shortness of Breath	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Difficulty Breathing	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Fatigue	None ☒	
v6.020 DTW (1102)	379 of 2112	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

	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	☐

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

Symptom Day

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	383 of 2112	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

	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	☐

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:31:01

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

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

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:31:01

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 _____

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:31:01

Neurologic Dysfunction? Yes ☐
No ☐

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☐

Date of Assessment

Radiographical Evidence Yes ☐
No ☐

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:31:01

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

US3522042

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:31:01

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

24 AUG 2020

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:31:01

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

21 SEP 2020

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:31:01

Visit Date

Please check all assessments that apply for this visit

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

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

Was the sample collected?

Yes ☐

No ☐

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3522042

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:31:01

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

AEID	USA-US131-2020-MRNA-1273-P30 1000001
Adverse event	SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☒ No ☐
Start date (dd MMM yyyy)	22 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	30 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	405 of 2112

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:31:01

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

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

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

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)	UN UNK 2012
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

Name of Medication	LORATADINE
Prophylaxis	Yes ☐ No ☒
Indication	SEASONAL ALLERGIES
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

	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)		
Start date completely unknown		True
Ongoing?		Yes ☒
		No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?		Yes ☐
		No ☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☒

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ☒
Indication	SYMPTOMATIC COVID-19
Dose per administration	650
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

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)	23 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy) 24 AUG 2020	
Was this medication taken for solicited event?	Yes ☐ No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☒

US3522042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:31:01

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3522042

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:31:01

Date of dosing discontinuation (dd MMM yyyy)

22 AUG 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☒

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify _____

US3522042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:31:01

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

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

SAEID	USA-US131-2020-MRNA-1273-P301000001
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:31:01

SAEID	USA-US131-2020-MRNA-1273-P301000001
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	24/AUG/2020 12:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:31:01

SAEID	USA-US131-2020-MRNA-1273-P301000001
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	31/AUG/2020 08:52
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:31:01

SAEID	USA-US131-2020-MRNA-1273-P301000001
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/SEP/2020 18:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:31:01

SAEID	USA-US131-2020-MRNA-1273-P301000001
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/SEP/2020 17:13
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3522042 (Prod: Henry Ford Health System)

US3522042

Form: Participant Creation

Generated On: 26 Nov 2020 09:31:01

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3522042'	RWS_ENDPOINT ENDPOINT (b) (4) 	07 Aug 2020 13:24:17

US3522042

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:34:38

US3522042

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	07 Aug 2020 13:24:18

US3522042

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:34:38

US3522042

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	07 Aug 2020 13:34:38

US3522042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:01

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1985'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 13:24:19

US3522042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:01

[Age](#)

Audit	User	Time (GMT)
User entered '34'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

US3522042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:01

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	07 Aug 2020 13:35:23

US3522042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:01

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '34'	System	07 Aug 2020 13:35:47

US3522042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:01

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

US3522042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:01

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

US3522042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:01

White

Audit	User	Time (GMT)
User entered '1'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

US3522042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:01

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

US3522042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:01

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

US3522042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:01

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

US3522042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:01

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

US3522042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:01

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

US3522042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:01

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

US3522042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:01

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

US3522042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:01

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:23

US3522042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:01

Date of Informed Consent (dd MMM yyyy)

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

US3522042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	07 Aug 2020 13:35:47

US3522042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '2020'	System	07 Aug 2020 13:35:47

US3522042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:01

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:47

US3522042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:47

US3522042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:47

US3522042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:01

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:47

US3522042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:01

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:47

US3522042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:01

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 13:24:18

US3522042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:01

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 13:35:53

US3522042

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:35:53

US3522042

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:31:01

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	28 Aug 2020 13:06:18
User entered 'No (N)'	Alandra White (b) (4)	07 Aug 2020 13:44:40

US3522042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 13:08:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 13:08:43
Data point term sent to Coder	System	28 Aug 2020 13:07:12
User entered 'Hypertension'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:06:27

US3522042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:06:27

US3522042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:06:27

US3522042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:06:27

US3522042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:01

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:06:27

US3522042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:06:27

US3522042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:01

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 13:06:27

US3522042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:01

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 13:06:27

US3522042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:01

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 13:06:27

US3522042

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:01

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 13:06:27

US3522042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:40:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:40:47
Data point term sent to Coder	System	14 Sep 2020 18:39:53
User entered 'Seasonal Allergies'	Sharon Mathys (b) (4)	14 Sep 2020 18:39:48
	(b) (4)	

US3522042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:39:48

US3522042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:39:48

US3522042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:39:48

US3522042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:01

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:39:48

US3522042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:39:48

US3522042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:01

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 18:39:48

US3522042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:01

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 18:39:48

US3522042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:01

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 18:39:48

US3522042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:01

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 18:39:48

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:59:19

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

Date of assessment (dd MMM yyyy)

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

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '09:55'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:59:19

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '07 Aug 2020 09:55'	System	06 Nov 2020 15:20:02
User entered '7 Aug 2020 09:55'	System	07 Aug 2020 13:59:19

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '67' in	Alandra White (b) (4)	07 Aug 2020 13:59:19
DataPoint set to visible.	(b) (4) System	07 Aug 2020 13:35:53

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '178.2' lb	Alandra White (b) (4)	07 Aug 2020 13:59:19
DataPoint set to visible.	(b) (4) System	07 Aug 2020 13:35:53

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '27.96842'	System	16 Sep 2020 23:46:54
User entered '28.0'	System	07 Aug 2020 13:59:19
DataPoint set to visible.	System	07 Aug 2020 13:35:53

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	07 Aug 2020 13:59:19
DataPoint set to visible.	System	07 Aug 2020 13:35:53

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	13 Aug 2020 14:26:24
User entered '98.3' F	Alandra White (b) (4)	07 Aug 2020 13:59:19

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Route of measurement](#)

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

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:59:19

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	13 Aug 2020 14:26:24
User entered '65'	Alandra White (b) (4)	07 Aug 2020 13:59:19

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Aug 2020 13:59:19

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	13 Aug 2020 14:26:24
User entered '14'	Alandra White (b) (4)	07 Aug 2020 13:59:19

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Aug 2020 13:59:19

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	13 Aug 2020 14:26:24
User entered '128'	Alandra White (b) (4)	07 Aug 2020 13:59:19

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Aug 2020 13:59:19

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	13 Aug 2020 14:26:24
User entered '91'	Alandra White (b) (4)	07 Aug 2020 13:59:19

US3522042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Aug 2020 13:59:19

US3522042

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:03:21

US3522042

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

Date of examination (dd MMM yyyy)

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

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

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)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

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)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

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)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

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)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

Other

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

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'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

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'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '1'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:01

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:05:39

US3522042

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:06:05

US3522042

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '07 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 19:23:26
User entered '7 Aug 2020'	Alandra White (b) (4)	07 Aug 2020 14:06:05

US3522042

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:06:05

US3522042

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	07 Aug 2020 14:06:05

US3522042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	07 Aug 2020 13:29:07

US3522042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:01

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:47:06
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:47:05
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 13:29:07
User entered '101710' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 13:29:07

US3522042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:01

[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) 	07 Aug 2020 13:29:07

US3522042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:01

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)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:06:14

US3522042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:06:14

US3522042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:06:14

US3522042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:01

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:06:14

US3522042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:01

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:06:14

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:01

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Sharon Mathys (b) (4)	13 Aug 2020 14:25:56
User entered '67' in reason for change: Per Query Resolution	Alandra White (b) (4)	07 Aug 2020 15:27:52
User entered empty.	Alandra White (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:01

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Sharon Mathys (b) (4)	13 Aug 2020 14:25:56
User entered '178.2' lb reason for change: Per Query Resolution	Alandra White (b) (4)	07 Aug 2020 15:27:52
User entered empty.	Alandra White (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:01

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Sharon Mathys (b) (4)	13 Aug 2020 14:25:56
User entered '67' in reason for change: Per Query Resolution	Alandra White (b) (4)	07 Aug 2020 15:27:52
User entered empty.	Alandra White (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:01

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Sharon Mathys (b) (4)	13 Aug 2020 14:25:56
User entered '178.2' lb reason for change: Per Query Resolution	Alandra White (b) (4)	07 Aug 2020 15:27:52
User entered empty.	Alandra White (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 15:27:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Aug 2020 15:27:52
User entered 'Yes (Y)' reason for change: Per Query Resolution	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:52
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 15:27:16
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Aug 2020'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '09:55'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '7 Aug 2020 09:55'	System	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

Pulse (xxx)

Audit	User	Time (GMT)
User entered '65'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '14'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '91'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:01

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Sharon Mathys (b) (4)	13 Aug 2020 14:25:56
User entered '67' in reason for change: Per Query Resolution	Alandra White (b) (4)	07 Aug 2020 15:27:52
User entered empty.	Alandra White (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:01

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Sharon Mathys (b) (4)	13 Aug 2020 14:25:56
User entered '178.2' lb reason for change: Per Query Resolution	Alandra White (b) (4)	07 Aug 2020 15:27:52
User entered empty.	Alandra White (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 15:27:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Aug 2020 15:27:52
User entered 'Yes (Y)' reason for change: Per Query Resolution	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:52
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 15:27:16
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Aug 2020'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User closed query 'Per CDM: the treatment time on the Exposure CRF is 11:00. The Vital Signs Post Dose Time of Assessment is 11:20. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 07:59:50
Query 'Per CDM: the treatment time on the Exposure CRF is 11:00. The Vital Signs Post Dose Time of Assessment is 11:20. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' answered with 'Exposure was 10:50 per source. Fixed' (Site from DM).	Sharon Mathys (b) (4)	23 Aug 2020 16:26:52
User opened query 'Per CDM: the treatment time on the Exposure CRF is 11:00. The Vital Signs Post Dose Time of Assessment is 11:20. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 11:31:49
Query 'Per CDM: The treatment time on the Exposure CRF is 11:11. The Vital Signs Post Dose Time of Assessment is 11:20. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' canceled (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 11:31:07
User opened query 'Per CDM: The treatment time on the Exposure CRF is 11:11. The Vital Signs Post Dose Time of Assessment is 11:20. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 11:30:40
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:29:54
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Reviewed' (Site from System).	mayur ramesh (b) (4)	11 Aug 2020 04:56:04
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		07 Aug 2020 15:27:16

v6.020 DTW (1102)

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US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '11:20'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '7 Aug 2020 11:20'	System	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '54'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '16'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '125'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '90'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Aug 2020 15:27:16

US3522042

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 15:41:27
User entered 'Yes (Y)'	Alandra White (b) (4)	07 Aug 2020 14:06:27

US3522042

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 15:41:27
User entered '7 Aug 2020'	Alandra White (b) (4)	07 Aug 2020 14:06:27

US3522042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:57:26

US3522042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:57:26

US3522042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:57:26

US3522042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 14:57:26

US3522042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '7 Aug 2020'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:57:26

US3522042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '10:50' reason for change: Data Entry Error	Sharon Mathys (b) (4)	23 Aug 2020 16:24:42
User entered '11:00' reason for change: Data Entry Error	Marcus Zervos (b) (4)	07 Aug 2020 15:03:58
User entered '10:50'	Alandra White (b) (4)	07 Aug 2020 14:57:26

US3522042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '7 Aug 2020 10:50'	System	23 Aug 2020 16:24:42
User entered '7 Aug 2020 11:00'	System	07 Aug 2020 15:03:58
User entered '7 Aug 2020 10:50'	System	07 Aug 2020 14:57:26

US3522042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:57:26

US3522042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	07 Aug 2020 14:57:26

US3522042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 14:57:26

US3522042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:10

US3522042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Aug 2020'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:10

US3522042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '09:47'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:10

US3522042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '7 Aug 2020 09:47'	System	07 Aug 2020 14:01:10

US3522042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:31:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Aug 2020'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:56

US3522042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:56

US3522042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:56

US3522042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:35'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:56

US3522042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '7 Aug 2020 09:35'	System	07 Aug 2020 14:01:56

US3522042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alandra White (b) (4)	07 Aug 2020 14:01:56

US3522042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:56

US3522042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 14:01:56

US3522042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 14:01:56

US3522042

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 15:34:57

US3522042

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 15:34:57

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

Was **TEMPERATURE** taken?

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

Please record your **TEMPERATURE** in °F

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

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

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

[PC Time Stamp](#)

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:20'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 11:10'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 13:50'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 13:40'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

Was **TEMPERATURE** taken?

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:50:31', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '5f68918a-94fe-4797-93ec-0536b58e3a3e'	System	07 Aug 2020 18:50:41
User entered '97.8'	System	07 Aug 2020 18:50:41

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

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

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

[PC Time Stamp](#)

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 14:45'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 14:35'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 2'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:01

Was **TEMPERATURE** taken?

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:01

Please record your **TEMPERATURE** in °F

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:04:09', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '935eb1ef-cefe-433a-801a-7f2d191fea95'	System	08 Aug 2020 16:04:14
User entered 'No (N)'	System	08 Aug 2020 16:04:14

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:01

[PC Time Stamp](#)

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 3'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:01

Was **TEMPERATURE** taken?

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:01

Please record your **TEMPERATURE** in °F

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:01

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

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:01

[PC Time Stamp](#)

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 4'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:01

Was **TEMPERATURE** taken?

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:01

Please record your **TEMPERATURE** in °F

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:01

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

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:01

[PC Time Stamp](#)

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 5'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:01

Was **TEMPERATURE** taken?

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:01

Please record your **TEMPERATURE** in °F

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:01

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

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:01

[PC Time Stamp](#)

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 6'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:01

Was **TEMPERATURE** taken?

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:01

Please record your **TEMPERATURE** in °F

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:01

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

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:01

[PC Time Stamp](#)

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 7'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:01

Was **TEMPERATURE** taken?

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:01

Please record your **TEMPERATURE** in °F

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:01

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

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:01

[PC Time Stamp](#)

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

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

[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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:20:58', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '37bc38f5-4516-4516-9a70-75f1030b7285'	System	07 Aug 2020 15:21:13
User entered 'None (1)'	System	07 Aug 2020 15:21:13

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

Is there any REDNESS AT INJECTION SITE?

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

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

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

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

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:09', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '37bc38f5-4516-4516-9a70-75f1030b7285'	System	07 Aug 2020 15:21:13
User entered 'None (1)'	System	07 Aug 2020 15:21:13

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

[PC Time Stamp](#)

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

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:20'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 11:10'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 13:50'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 13:40'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:22', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '73ed35ec-8719-4f5f-b235-8d54f2fd0037'	System	07 Aug 2020 18:45:38
User entered 'None (1)'	System	07 Aug 2020 18:45:38

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:24', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '73ed35ec-8719-4f5f-b235-8d54f2fd0037'	System	07 Aug 2020 18:45:38
User entered 'No (N)'	System	07 Aug 2020 18:45:38

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:25', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '73ed35ec-8719-4f5f-b235-8d54f2fd0037'	System	07 Aug 2020 18:45:38
User entered 'No (N)'	System	07 Aug 2020 18:45:38

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:32', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '73ed35ec-8719-4f5f-b235-8d54f2fd0037'	System	07 Aug 2020 18:45:38
User entered 'None (1)'	System	07 Aug 2020 18:45:38

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:34', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '73ed35ec-8719-4f5f-b235-8d54f2fd0037'	System	07 Aug 2020 18:45:38
User entered '07 Aug 2020 14:45'	System	07 Aug 2020 18:45:38

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 14:45'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 14:35'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 2'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:29', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6dfdbe9f-beb1-4586-9cfa-48b63f5e5817'	System	08 Aug 2020 16:00:38
User entered 'None (1)'	System	08 Aug 2020 16:00:38

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:31', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6dfdbe9f-beb1-4586-9cfa-48b63f5e5817'	System	08 Aug 2020 16:00:38
User entered 'No (N)'	System	08 Aug 2020 16:00:38

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:32', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6dfdbe9f-beb1-4586-9cfa-48b63f5e5817'	System	08 Aug 2020 16:00:38
User entered 'No (N)'	System	08 Aug 2020 16:00:38

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:34', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6dfdbe9f-beb1-4586-9cfa-48b63f5e5817'	System	08 Aug 2020 16:00:38
User entered 'None (1)'	System	08 Aug 2020 16:00:38

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:37', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6dfdbe9f-beb1-4586-9cfa-48b63f5e5817'	System	08 Aug 2020 16:00:38
User entered '08 Aug 2020 12:00'	System	08 Aug 2020 16:00:38

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 3'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:21', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '7926e932-2b9e-4ec9-ac4e-6a17b7372212'	System	09 Aug 2020 18:45:36
User entered 'None (1)'	System	09 Aug 2020 18:45:36

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:23', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '7926e932-2b9e-4ec9-ac4e-6a17b7372212'	System	09 Aug 2020 18:45:36
User entered 'No (N)'	System	09 Aug 2020 18:45:36

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:26', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '7926e932-2b9e-4ec9-ac4e-6a17b7372212'	System	09 Aug 2020 18:45:36
User entered 'No (N)'	System	09 Aug 2020 18:45:36

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:28', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '7926e932-2b9e-4ec9-ac4e-6a17b7372212'	System	09 Aug 2020 18:45:36
User entered 'None (1)'	System	09 Aug 2020 18:45:36

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:31', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '7926e932-2b9e-4ec9-ac4e-6a17b7372212'	System	09 Aug 2020 18:45:36
User entered '09 Aug 2020 14:45'	System	09 Aug 2020 18:45:36

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 4'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:07', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'ed03ce1a-ce1d-499e-823c-3763103c3754'	System	10 Aug 2020 20:07:22
User entered 'None (1)'	System	10 Aug 2020 20:07:22

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:09', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'ed03ce1a-ce1d-499e-823c-3763103c3754'	System	10 Aug 2020 20:07:22
User entered 'No (N)'	System	10 Aug 2020 20:07:22

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:11', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'ed03ce1a-ce1d-499e-823c-3763103c3754'	System	10 Aug 2020 20:07:22
User entered 'No (N)'	System	10 Aug 2020 20:07:22

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:16', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'ed03ce1a-ce1d-499e-823c-3763103c3754'	System	10 Aug 2020 20:07:22
User entered 'None (1)'	System	10 Aug 2020 20:07:22

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:20', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'ed03ce1a-ce1d-499e-823c-3763103c3754' User entered '10 Aug 2020 16:07'	System	10 Aug 2020 20:07:22
	System	10 Aug 2020 20:07:22

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 5'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:22:27', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '4855852d-67c8-48fc-a383-1903e3152d25'	System	11 Aug 2020 16:22:40
User entered 'None (1)'	System	11 Aug 2020 16:22:40

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:22:28', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '4855852d-67c8-48fc-a383-1903e3152d25'	System	11 Aug 2020 16:22:40
User entered 'No (N)'	System	11 Aug 2020 16:22:40

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:22:30', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '4855852d-67c8-48fc-a383-1903e3152d25'	System	11 Aug 2020 16:22:40
User entered 'No (N)'	System	11 Aug 2020 16:22:40

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:22:32', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '4855852d-67c8-48fc-a383-1903e3152d25'	System	11 Aug 2020 16:22:40
User entered 'None (1)'	System	11 Aug 2020 16:22:40

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:22:37', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '4855852d-67c8-48fc-a383-1903e3152d25'	System	11 Aug 2020 16:22:40
User entered '11 Aug 2020 12:22'	System	11 Aug 2020 16:22:40

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 6'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:00', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '55827b53-9e07-4356-878c-6317f733ab34'	System	12 Aug 2020 17:50:10
User entered 'None (1)'	System	12 Aug 2020 17:50:10

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:01', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '55827b53-9e07-4356-878c-6317f733ab34'	System	12 Aug 2020 17:50:10
User entered 'No (N)'	System	12 Aug 2020 17:50:10

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:02', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '55827b53-9e07-4356-878c-6317f733ab34'	System	12 Aug 2020 17:50:10
User entered 'No (N)'	System	12 Aug 2020 17:50:10

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:04', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '55827b53-9e07-4356-878c-6317f733ab34'	System	12 Aug 2020 17:50:10
User entered 'None (1)'	System	12 Aug 2020 17:50:10

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:06', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '55827b53-9e07-4356-878c-6317f733ab34'	System	12 Aug 2020 17:50:10
User entered '12 Aug 2020 13:50'	System	12 Aug 2020 17:50:10

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 7'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:44', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e2b65a6b-f29f-47af-950b-78b25fa38921'	System	13 Aug 2020 16:18:51
User entered 'None (1)'	System	13 Aug 2020 16:18:51

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:45', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e2b65a6b-f29f-47af-950b-78b25fa38921'	System	13 Aug 2020 16:18:51
User entered 'No (N)'	System	13 Aug 2020 16:18:51

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:47', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e2b65a6b-f29f-47af-950b-78b25fa38921'	System	13 Aug 2020 16:18:51
User entered 'No (N)'	System	13 Aug 2020 16:18:51

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:48', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e2b65a6b-f29f-47af-950b-78b25fa38921'	System	13 Aug 2020 16:18:51
User entered 'None (1)'	System	13 Aug 2020 16:18:51

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:50', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e2b65a6b-f29f-47af-950b-78b25fa38921'	System	13 Aug 2020 16:18:51
User entered '13 Aug 2020 12:18'	System	13 Aug 2020 16:18:51

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:15', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'abb5d09a-322e-4aad-b946-8fc535617fca'	System	07 Aug 2020 15:21:34
User entered 'None (0)'	System	07 Aug 2020 15:21:34

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:19', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'abb5d09a-322e-4aad-b946-8fc535617fca'	System	07 Aug 2020 15:21:34
User entered 'None (0)'	System	07 Aug 2020 15:21:34

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:21', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'abb5d09a-322e-4aad-b946-8fc535617fca'	System	07 Aug 2020 15:21:34
User entered 'None (0)'	System	07 Aug 2020 15:21:34

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:23', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'abb5d09a-322e-4aad-b946-8fc535617fca' User entered 'None (0)'	System	07 Aug 2020 15:21:34
	System	07 Aug 2020 15:21:34

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:24', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'abb5d09a-322e-4aad-b946-8fc535617fca'	System	07 Aug 2020 15:21:34
User entered 'None (0)'	System	07 Aug 2020 15:21:34

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:26', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'abb5d09a-322e-4aad-b946-8fc535617fca'	System	07 Aug 2020 15:21:34
User entered 'None (0)'	System	07 Aug 2020 15:21:34

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:30', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'abb5d09a-322e-4aad-b946-8fc535617fca'	System	07 Aug 2020 15:21:34
User entered 'No (N)'	System	07 Aug 2020 15:21:34

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T11:21:32', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'abb5d09a-322e-4aad-b946-8fc535617fca' User entered '07 Aug 2020 11:21'	System	07 Aug 2020 15:21:34
	System	07 Aug 2020 15:21:34

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:20'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 11:10'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 13:50'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 13:40'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:37', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '87ed26de-0444-4078-8ed9-e87ad7a48535'	System	07 Aug 2020 18:45:54
User entered 'None (0)'	System	07 Aug 2020 18:45:54

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:39', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '87ed26de-0444-4078-8ed9-e87ad7a48535'	System	07 Aug 2020 18:45:54
User entered 'None (0)'	System	07 Aug 2020 18:45:54

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:43', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '87ed26de-0444-4078-8ed9-e87ad7a48535'	System	07 Aug 2020 18:45:54
User entered 'No interference with activity (1)'	System	07 Aug 2020 18:45:54

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:45', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '87ed26de-0444-4078-8ed9-e87ad7a48535'	System	07 Aug 2020 18:45:54
User entered 'None (0)'	System	07 Aug 2020 18:45:54

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:46', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '87ed26de-0444-4078-8ed9-e87ad7a48535'	System	07 Aug 2020 18:45:54
User entered 'None (0)'	System	07 Aug 2020 18:45:54

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:48', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '87ed26de-0444-4078-8ed9-e87ad7a48535'	System	07 Aug 2020 18:45:54
User entered 'None (0)'	System	07 Aug 2020 18:45:54

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:51', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '87ed26de-0444-4078-8ed9-e87ad7a48535'	System	07 Aug 2020 18:45:54
User entered 'No (N)'	System	07 Aug 2020 18:45:54

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-07T14:45:53', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '87ed26de-0444-4078-8ed9-e87ad7a48535'	System	07 Aug 2020 18:45:54
User entered '07 Aug 2020 14:45'	System	07 Aug 2020 18:45:54

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 14:45'	System	07 Aug 2020 15:03:58
User entered '07 Aug 2020 14:35'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:01

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 2'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:39', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e684ada7-271d-496b-813e-dd3033730b91'	System	08 Aug 2020 16:00:55
User entered 'None (0)'	System	08 Aug 2020 16:00:55

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:41', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e684ada7-271d-496b-813e-dd3033730b91'	System	08 Aug 2020 16:00:55
User entered 'None (0)'	System	08 Aug 2020 16:00:55

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:42', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e684ada7-271d-496b-813e-dd3033730b91'	System	08 Aug 2020 16:00:55
User entered 'None (0)'	System	08 Aug 2020 16:00:55

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:44', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e684ada7-271d-496b-813e-dd3033730b91'	System	08 Aug 2020 16:00:55
User entered 'None (0)'	System	08 Aug 2020 16:00:55

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:45', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e684ada7-271d-496b-813e-dd3033730b91'	System	08 Aug 2020 16:00:55
User entered 'None (0)'	System	08 Aug 2020 16:00:55

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:46', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e684ada7-271d-496b-813e-dd3033730b91'	System	08 Aug 2020 16:00:55
User entered 'None (0)'	System	08 Aug 2020 16:00:55

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:48', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e684ada7-271d-496b-813e-dd3033730b91'	System	08 Aug 2020 16:00:55
User entered 'No (N)'	System	08 Aug 2020 16:00:55

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-08T12:00:53', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'e684ada7-271d-496b-813e-dd3033730b91'	System	08 Aug 2020 16:00:55
User entered '08 Aug 2020 12:00'	System	08 Aug 2020 16:00:55

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 3'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:44:46', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '1b97e425-cd0f-411e-a0b7-255d5fe83b64'	System	09 Aug 2020 18:45:20
User entered 'None (0)'	System	09 Aug 2020 18:45:20

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:44:51', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '1b97e425-cd0f-411e-a0b7-255d5fe83b64'	System	09 Aug 2020 18:45:20
User entered 'None (0)'	System	09 Aug 2020 18:45:20

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:44:54', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '1b97e425-cd0f-411e-a0b7-255d5fe83b64'	System	09 Aug 2020 18:45:20
User entered 'None (0)'	System	09 Aug 2020 18:45:20

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:44:57', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '1b97e425-cd0f-411e-a0b7-255d5fe83b64'	System	09 Aug 2020 18:45:20
User entered 'None (0)'	System	09 Aug 2020 18:45:20

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:00', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '1b97e425-cd0f-411e-a0b7-255d5fe83b64'	System	09 Aug 2020 18:45:20
User entered 'None (0)'	System	09 Aug 2020 18:45:20

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:02', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '1b97e425-cd0f-411e-a0b7-255d5fe83b64'	System	09 Aug 2020 18:45:20
User entered 'None (0)'	System	09 Aug 2020 18:45:20

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:07', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '1b97e425-cd0f-411e-a0b7-255d5fe83b64'	System	09 Aug 2020 18:45:20
User entered 'No (N)'	System	09 Aug 2020 18:45:20

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-09T14:45:15', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '1b97e425-cd0f-411e-a0b7-255d5fe83b64'	System	09 Aug 2020 18:45:20
User entered '09 Aug 2020 14:45'	System	09 Aug 2020 18:45:20

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 4'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:23', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '76d6511d-ed8a-4b99-83a9-92c3313193c6'	System	10 Aug 2020 20:07:41
User entered 'None (0)'	System	10 Aug 2020 20:07:41

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:24', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '76d6511d-ed8a-4b99-83a9-92c3313193c6'	System	10 Aug 2020 20:07:41
User entered 'None (0)'	System	10 Aug 2020 20:07:41

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:28', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '76d6511d-ed8a-4b99-83a9-92c3313193c6'	System	10 Aug 2020 20:07:41
User entered 'None (0)'	System	10 Aug 2020 20:07:41

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:32', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '76d6511d-ed8a-4b99-83a9-92c3313193c6'	System	10 Aug 2020 20:07:41
User entered 'None (0)'	System	10 Aug 2020 20:07:41

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:34', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '76d6511d-ed8a-4b99-83a9-92c3313193c6'	System	10 Aug 2020 20:07:41
User entered 'None (0)'	System	10 Aug 2020 20:07:41

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:36', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '76d6511d-ed8a-4b99-83a9-92c3313193c6'	System	10 Aug 2020 20:07:41
User entered 'None (0)'	System	10 Aug 2020 20:07:41

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:38', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '76d6511d-ed8a-4b99-83a9-92c3313193c6'	System	10 Aug 2020 20:07:41
User entered 'No (N)'	System	10 Aug 2020 20:07:41

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-10T16:07:39', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '76d6511d-ed8a-4b99-83a9-92c3313193c6'	System	10 Aug 2020 20:07:41
User entered '10 Aug 2020 16:07'	System	10 Aug 2020 20:07:41

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 5'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:23:19', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '942c3133-8a06-4129-a41d-215cd0fd9c3e'	System	11 Aug 2020 16:23:43
User entered 'None (0)'	System	11 Aug 2020 16:23:43

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:23:21', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '942c3133-8a06-4129-a41d-215cd0fd9c3e'	System	11 Aug 2020 16:23:43
User entered 'None (0)'	System	11 Aug 2020 16:23:43

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:23:22', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '942c3133-8a06-4129-a41d-215cd0fd9c3e'	System	11 Aug 2020 16:23:43
User entered 'None (0)'	System	11 Aug 2020 16:23:43

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:23:24', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '942c3133-8a06-4129-a41d-215cd0fd9c3e'	System	11 Aug 2020 16:23:43
User entered 'None (0)'	System	11 Aug 2020 16:23:43

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:23:25', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '942c3133-8a06-4129-a41d-215cd0fd9c3e'	System	11 Aug 2020 16:23:43
User entered 'None (0)'	System	11 Aug 2020 16:23:43

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:23:34', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '942c3133-8a06-4129-a41d-215cd0fd9c3e'	System	11 Aug 2020 16:23:43
User entered 'None (0)'	System	11 Aug 2020 16:23:43

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:23:36', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '942c3133-8a06-4129-a41d-215cd0fd9c3e'	System	11 Aug 2020 16:23:43
User entered 'No (N)'	System	11 Aug 2020 16:23:43

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-11T12:23:38', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '942c3133-8a06-4129-a41d-215cd0fd9c3e'	System	11 Aug 2020 16:23:43
User entered '11 Aug 2020 12:23'	System	11 Aug 2020 16:23:43

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 6'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:08', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '116ba212-9f8d-488d-89d0-4b983d04c956'	System	12 Aug 2020 17:50:18
User entered 'None (0)'	System	12 Aug 2020 17:50:18

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:09', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '116ba212-9f8d-488d-89d0-4b983d04c956'	System	12 Aug 2020 17:50:18
User entered 'None (0)'	System	12 Aug 2020 17:50:18

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:10', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '116ba212-9f8d-488d-89d0-4b983d04c956'	System	12 Aug 2020 17:50:18
User entered 'None (0)'	System	12 Aug 2020 17:50:18

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:11', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '116ba212-9f8d-488d-89d0-4b983d04c956'	System	12 Aug 2020 17:50:18
User entered 'None (0)'	System	12 Aug 2020 17:50:18

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:13', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '116ba212-9f8d-488d-89d0-4b983d04c956'	System	12 Aug 2020 17:50:18
User entered 'None (0)'	System	12 Aug 2020 17:50:18

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:14', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '116ba212-9f8d-488d-89d0-4b983d04c956'	System	12 Aug 2020 17:50:18
User entered 'None (0)'	System	12 Aug 2020 17:50:18

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:15', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '116ba212-9f8d-488d-89d0-4b983d04c956'	System	12 Aug 2020 17:50:18
User entered 'No (N)'	System	12 Aug 2020 17:50:18

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-12T13:50:17', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '116ba212-9f8d-488d-89d0-4b983d04c956'	System	12 Aug 2020 17:50:18
User entered '12 Aug 2020 13:50'	System	12 Aug 2020 17:50:18

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 7'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:52', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6c30bb3d-8580-4d6e-ad30-daad633d0395'	System	13 Aug 2020 16:19:08
User entered 'None (0)'	System	13 Aug 2020 16:19:08

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:53', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6c30bb3d-8580-4d6e-ad30-daad633d0395'	System	13 Aug 2020 16:19:08
User entered 'None (0)'	System	13 Aug 2020 16:19:08

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:55', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6c30bb3d-8580-4d6e-ad30-daad633d0395'	System	13 Aug 2020 16:19:08
User entered 'None (0)'	System	13 Aug 2020 16:19:08

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:56', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6c30bb3d-8580-4d6e-ad30-daad633d0395'	System	13 Aug 2020 16:19:08
User entered 'None (0)'	System	13 Aug 2020 16:19:08

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:57', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6c30bb3d-8580-4d6e-ad30-daad633d0395'	System	13 Aug 2020 16:19:08
User entered 'None (0)'	System	13 Aug 2020 16:19:08

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:58', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6c30bb3d-8580-4d6e-ad30-daad633d0395'	System	13 Aug 2020 16:19:08
User entered 'None (0)'	System	13 Aug 2020 16:19:08

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:01

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 (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:18:59', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6c30bb3d-8580-4d6e-ad30-daad633d0395'	System	13 Aug 2020 16:19:08
User entered 'No (N)'	System	13 Aug 2020 16:19:08

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-08-13T12:19:02', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '6c30bb3d-8580-4d6e-ad30-daad633d0395'	System	13 Aug 2020 16:19:08
User entered '13 Aug 2020 12:19'	System	13 Aug 2020 16:19:08

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 14:57:26

US3522042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	14 Aug 2020 14:42:44
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	14 Aug 2020 14:40:32
User entered 'Yes (Y)'	Kristin Eis (b) (4) [REDACTED]	14 Aug 2020 14:40:32

US3522042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Aug 2020'	Kristin Eis (b) (4) [REDACTED]	14 Aug 2020 14:40:32

US3522042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 14:42:44
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:40:32

US3522042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Attempted to call patient, did not answer; voicemail was left' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 14:42:44
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:40:32

US3522042

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) [REDACTED]	14 Aug 2020 14:40:39

US3522042

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 14:40:39

US3522042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4) (b) (4)	21 Aug 2020 18:58:21

US3522042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	Jo-Ann Rammal (b) (4) (b) (4)	21 Aug 2020 18:58:21

US3522042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4) (b) (4)	21 Aug 2020 19:26:40
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jo-Ann Rammal (b) (4) (b) (4)	21 Aug 2020 18:58:21

US3522042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Pt is good, no adverse events' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4)	21 Aug 2020 19:26:40
User entered 'Left voice message'	Jo-Ann Rammal (b) (4)	21 Aug 2020 18:58:21

US3522042

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4) (b) (4)	21 Aug 2020 19:26:46

US3522042

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:26:46

US3522042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:49:40

US3522042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6) [REDACTED]	28 Sep 2020 18:49:40

US3522042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:49:40

US3522042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:49:40

US3522042

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:50:23
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	21 Sep 2020 16:50:57

US3522042

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:50:23
User entered '1'	System	21 Sep 2020 16:50:57

US3522042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:05

US3522042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:05

US3522042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

[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)	21 Sep 2020 16:51:05

US3522042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	21 Sep 2020 16:51:05

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:01

[Height](#)

Audit	User	Time (GMT)
DataPoint set to visible.	System	28 Sep 2020 18:50:23
DataPoint set to invisible.	System	21 Sep 2020 16:50:57

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:01

[Weight](#)

Audit	User	Time (GMT)
DataPoint set to visible.	System	28 Sep 2020 18:50:23
DataPoint set to invisible.	System	21 Sep 2020 16:50:57

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:01

[Height](#)

Audit	User	Time (GMT)
DataPoint set to visible.	System	28 Sep 2020 18:50:23
DataPoint set to invisible.	System	21 Sep 2020 16:50:57

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:01

[Weight](#)

Audit	User	Time (GMT)
DataPoint set to visible.	System	28 Sep 2020 18:50:23
DataPoint set to invisible.	System	21 Sep 2020 16:50:57

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:01

[Height](#)

Audit	User	Time (GMT)
DataPoint set to visible.	System	28 Sep 2020 18:50:23
DataPoint set to invisible.	System	21 Sep 2020 16:50:57

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:01

[Weight](#)

Audit	User	Time (GMT)
DataPoint set to visible.	System	28 Sep 2020 18:50:23
DataPoint set to invisible.	System	21 Sep 2020 16:50:57

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:52:14

US3522042

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:40

US3522042

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:40

US3522042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:35

US3522042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered 'Confirmed COVID-19 (COVID)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:35

US3522042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

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)	21 Sep 2020 16:51:35

US3522042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:51:35

US3522042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:35

US3522042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:35

US3522042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:51:35

US3522042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:35

US3522042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:51:35

US3522042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:51:35

US3522042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:24

US3522042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:24

US3522042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:24

US3522042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:51:24

US3522042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:31:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:16

US3522042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:16

US3522042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:16

US3522042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:16

US3522042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:51:16

US3522042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:16

US3522042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:16

US3522042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	21 Sep 2020 16:51:16

US3522042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:51:16

US3522042

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:50:12
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	21 Sep 2020 16:51:10

US3522042

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:50:12
User entered '1'	System	21 Sep 2020 16:51:10

US3522042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	21 Sep 2020 17:19:05

US3522042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Tyler Prentiss (b) (4) (b) (4)	21 Sep 2020 17:19:05

US3522042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[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)	21 Sep 2020 17:19:05

US3522042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Patient was COVID-positive; physician Tyler Prentiss (b) (4) Dr. Ramesh was performing active telemedicine and (b) (4) illness visits in lieu of safety phone calls'	(b) (4)	21 Sep 2020 17:19:05

US3522042

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	21 Sep 2020 17:19:09

US3522042

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:19:09

US3522042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	21 Sep 2020 17:19:35

US3522042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Tyler Prentiss (b) (4) (b) (4)	21 Sep 2020 17:19:35

US3522042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[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)	21 Sep 2020 17:19:35

US3522042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Patient was COVID-positive; physician Tyler Prentiss (b) (4) Dr. Ramesh was performing active telemedicine and (b) (4) illness visits in lieu of safety phone calls'	(b) (4)	21 Sep 2020 17:19:35

US3522042

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	21 Sep 2020 17:19:39

US3522042

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:19:39

US3522042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) [REDACTED]	24 Sep 2020 16:56:45

US3522042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020' reason for change: Data Entry Error	Kristin Eis (b) (4)	29 Sep 2020 18:19:43
User entered '24 Sep 2020'	Kristin Eis (b) (4)	24 Sep 2020 16:56:45

US3522042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Kristin Eis (b) (4) [REDACTED]	29 Sep 2020 18:19:43
User entered 'Contact Not Made (CONTACT NOT MADE)'	Kristin Eis (b) (4) [REDACTED]	24 Sep 2020 16:56:45

US3522042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'patient was covid positive, did not receive second dosage has been doing illness visits with study doctor.' reason for change: Data Entry Error	Kristin Eis (b) (4)	29 Sep 2020 18:19:43
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).		24 Sep 2020 16:58:22
User entered 'patient did not answer; voicemail was left' reason for change: Data Entry Error	Kristin Eis (b) (4)	24 Sep 2020 16:58:22
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	24 Sep 2020 16:56:45
User entered empty.	Kristin Eis (b) (4)	24 Sep 2020 16:56:45

US3522042

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) [REDACTED]	24 Sep 2020 16:57:45

US3522042

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 16:57:45

US3522042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:54:24

US3522042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:54:24

US3522042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 17:08:43
User entered 'Home (Home)'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:54:24

US3522042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	02 Oct 2020 16:54:24

US3522042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

US3522042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG, Date of assessment should be recorded in (dd-MMM-yyyy) format. Please review and update it accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:32:20
Query 'Per CDM: Per CCG, Date of assessment should be recorded in (dd-MMM-yyyy) format. Please review and update it accordingly. ' answered with 'Please fix medidata. The auto calendar button was used and formats the date as d MMM yyyy. Don't provide a calendar option if it does not format the way you want.' (Site from DM).	Sharon Mathys (b) (4)	06 Nov 2020 15:20:27
User entered '02 Oct 2020' reason for change: Per Query Resolution	(b) (4)	06 Nov 2020 15:20:22
User opened query 'Per CDM: Per CCG, Date of assessment should be recorded in (dd-MMM-yyyy) format. Please review and update it accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:44:29
User entered '2 Oct 2020'	Sharon Mathys (b) (4)	02 Oct 2020 16:57:07

US3522042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG, Time of assessment should be recorded in 24 HR format (HH:MM) .Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:32:26
Query 'Per CDM: Per CCG, Time of assessment should be recorded in 24 HR format (HH:MM) .Please review and update accordingly.' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4)	06 Nov 2020 15:20:31
User entered '09:30' reason for change: Per Query Resolution	(b) (4)	
User opened query 'Per CDM: Per CCG, Time of assessment should be recorded in 24 HR format (HH:MM) .Please review and update accordingly.' (Site from DM).	Sharon Mathys (b) (4)	06 Nov 2020 15:20:22
User entered '9:30'	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 13:46:14
	Sharon Mathys (b) (4)	02 Oct 2020 16:57:07
	(b) (4)	

US3522042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '02 Oct 2020 09:30'	System	06 Nov 2020 15:20:22
User entered '2 Oct 2020 9:30'	System	02 Oct 2020 16:57:07

US3522042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.6' F	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

US3522042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

US3522042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

US3522042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '59'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

US3522042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Oct 2020 16:57:07

US3522042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '16'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

US3522042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Oct 2020 16:57:07

US3522042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '137'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

US3522042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 16:57:07

US3522042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '79'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:07

US3522042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 16:57:07

US3522042

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:54:36

US3522042

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:54:36

US3522042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:26

US3522042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:26

US3522042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '09:40'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:57:26

US3522042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '2 Oct 2020 09:40'	System	02 Oct 2020 16:57:26

US3522042

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	02 Oct 2020 16:54:42

US3522042

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 16:54:42

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 64'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-11T10:07:41', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '7c82ec6c-2acf-4fb9-ac06-7962c86c23ab' User entered 'No (N)'	System	11 Oct 2020 14:07:51
	System	11 Oct 2020 14:07:51

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-11T10:07:45', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '7c82ec6c-2acf-4fb9-ac06-7962c86c23ab' User entered 'No (N)'	System	11 Oct 2020 14:07:51
	System	11 Oct 2020 14:07:51

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-11T10:07:47', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '7c82ec6c-2acf-4fb9-ac06-7962c86c23ab' User entered '11 Oct 2020 10:07:47'	System	11 Oct 2020 14:07:51
	System	11 Oct 2020 14:07:51

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 71'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-14T06:30:52', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'da48d99e-65f9-4224-a60b-e7a232097ce7'	System	14 Oct 2020 10:31:02
User entered 'No (N)'	System	14 Oct 2020 10:31:02

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-14T06:30:54', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'da48d99e-65f9-4224-a60b-e7a232097ce7'	System	14 Oct 2020 10:31:02
User entered 'No (N)'	System	14 Oct 2020 10:31:02

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-14T06:30:58', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: 'da48d99e-65f9-4224-a60b-e7a232097ce7'	System	14 Oct 2020 10:31:02
User entered '14 Oct 2020 06:30:58'	System	14 Oct 2020 10:31:02

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 78'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-21T05:31:56', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '769200a0-5b98-41a1-8c92-9666d04a5616'	System	21 Oct 2020 09:32:06
User entered 'No (N)'	System	21 Oct 2020 09:32:06

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-21T05:32:00', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '769200a0-5b98-41a1-8c92-9666d04a5616'	System	21 Oct 2020 09:32:06
User entered 'No (N)'	System	21 Oct 2020 09:32:06

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-10-21T05:32:02', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '769200a0-5b98-41a1-8c92-9666d04a5616' User entered '21 Oct 2020 05:32:02'	System	21 Oct 2020 09:32:06
	System	21 Oct 2020 09:32:06

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 92'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-05T12:02:05', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '3c9e8a34-f0a3-4750-80de-5041fb48d9de'	System	05 Nov 2020 17:04:31
User entered 'No (N)'	System	05 Nov 2020 17:04:31

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-05T12:02:09', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '3c9e8a34-f0a3-4750-80de-5041fb48d9de'	System	05 Nov 2020 17:04:31
User entered 'No (N)'	System	05 Nov 2020 17:04:31

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-05T12:02:11', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '3c9e8a34-f0a3-4750-80de-5041fb48d9de' User entered '05 Nov 2020 12:02:11'	System	05 Nov 2020 17:04:31
	System	05 Nov 2020 17:04:31

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 99'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-11T00:01:39', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '823633a8-ff83-4871-a895-46c7833d4206'	System	11 Nov 2020 05:01:52
User entered 'No (N)'	System	11 Nov 2020 05:01:52

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-11T00:01:43', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '823633a8-ff83-4871-a895-46c7833d4206'	System	11 Nov 2020 05:01:52
User entered 'No (N)'	System	11 Nov 2020 05:01:52

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-11T00:01:45', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '823633a8-ff83-4871-a895-46c7833d4206'	System	11 Nov 2020 05:01:52
User entered '11 Nov 2020 00:01:45'	System	11 Nov 2020 05:01:52

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered 'Day 106'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-18T07:43:02', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '57ed8f1f-a786-4527-8ab8-57b7a20815f3'	System	18 Nov 2020 12:43:08
User entered 'No (N)'	System	18 Nov 2020 12:43:08

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-18T07:43:04', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '57ed8f1f-a786-4527-8ab8-57b7a20815f3'	System	18 Nov 2020 12:43:08
User entered 'No (N)'	System	18 Nov 2020 12:43:08

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1A786B42-3AB8-4137-8681-6611506FF868)', Time: '2020-11-18T07:43:06', User OID: 'PatientReportedOutcome (US3522042)', ODM File OID: '57ed8f1f-a786-4527-8ab8-57b7a20815f3'	System	18 Nov 2020 12:43:08
User entered '18 Nov 2020 07:43:06'	System	18 Nov 2020 12:43:08

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 14:57:26

US3522042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 14:57:26
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 14:57:26

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '04 Oct 2020 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '08 Oct 2020 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '11 Oct 2020 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '15 Oct 2020 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '18 Oct 2020 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '22 Oct 2020 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '25 Oct 2020 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '29 Oct 2020 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '01 Nov 2020 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '05 Nov 2020 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '08 Nov 2020 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '12 Nov 2020 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 15:35:25

US3522042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:35:25
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 15:35:25

US3522042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	29 Oct 2020 14:12:48

US3522042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Yaman Ahmed (b) (4) (b) (4)	29 Oct 2020 14:12:48

US3522042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	Yaman Ahmed (b) (4) (b) (4)	29 Oct 2020 14:12:48

US3522042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'left a voicemail'	Yaman Ahmed (b) (4) (b) (4)	29 Oct 2020 14:12:48

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:31:01

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:10
User entered '24 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 13:59:57

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:31:01

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:10
User entered '09:00'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 13:59:57

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:31:01

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 09:00'	System	24 Aug 2020 13:59:57

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:31:01

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:10
User entered 'Safety Call (Safety Call)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 13:59:57

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:31:01

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:10
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 13:59:57

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please confirm initial start date of symptoms and Contact date are the same (24AUG2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 01:44:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
Query 'Per CDM: Please confirm initial start date of symptoms and Contact date are the same (24AUG2020) or update accordingly' answered with 'Symptoms began August 22' (Site from DM).	Alayna Wilder (b) (4)	09 Nov 2020 18:56:15
User entered '22 Aug 2020' reason for change: Data Entry Error	Alayna Wilder (b) (4)	09 Nov 2020 18:55:50
User opened query 'Per CDM: Please confirm initial start date of symptoms and Contact date are the same (24AUG2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:51:58
User entered '24 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:25:02
User entered '22 Aug 2020'	Sharon Mathys (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:25:02
User entered '1'	Sharon Mathys (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:25:02
User entered empty.	Sharon Mathys (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	26 Aug 2020 15:25:02
User entered empty.	System	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.3' F reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:25:02
User entered '100.9' F reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Aug 2020 14:12:30
User entered empty.	Sharon Mathys (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:25:02
User entered 'Mild (Mild)'	Sharon Mathys (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:25:02
User entered 'Mild (Mild)'	Sharon Mathys (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'Mild (Mild)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:25:02
User entered 'None (None)'	Sharon Mathys (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:25:02
User entered 'Mild (Mild)'	Sharon Mathys (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:28:12
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:25:02
User entered 'Moderate (Moderate)'	Sharon Mathys (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Aug 2020 14:12:30
User entered empty.	Sharon Mathys (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Aug 2020 14:12:30
User entered empty.	Sharon Mathys (b) (4)	24 Aug 2020 14:11:58

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '25 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:28:02
User entered '23 Aug 2020'	Sharon Mathys (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:28:02
User entered '1'	Sharon Mathys (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:28:02
User entered empty.	Sharon Mathys (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	26 Aug 2020 15:28:02
User entered empty.	System	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.1' F reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:28:02
User entered '99' F	Sharon Mathys (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:28:02
User entered 'Mild (Mild)'	Sharon Mathys (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:28:02
User entered 'None (None)'	Sharon Mathys (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'Moderate (Moderate)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:15:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '26 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.9' F	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:30:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '27 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.1' F	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:55:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '28 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.5' F	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:56:17

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '29 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.9' F	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:31:42

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '30 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98' F	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:33:13

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '31 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97' F	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	31 Aug 2020 17:34:35
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	31 Aug 2020 17:34:35
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	31 Aug 2020 17:34:35

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '1 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98.3' F	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	01 Sep 2020 16:09:46
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 16:09:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '2 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.9' F	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:47:46
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:47:46
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:47:46
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:47:46
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:47:46

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '3 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Sep 2020 12:48:15

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98.2' F	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:48:15
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:48:15
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:48:15
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:48:15
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:48:15

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:48:15

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:48:15
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:48:15

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '4 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Sep 2020 12:49:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.9' F	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:49:22
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:49:22
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:49:22
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:49:22
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:49:22
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:49:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:49:22
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:49:22
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:49:22

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '5 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Sep 2020 12:50:31

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98.1' F	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:50:31
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:50:31
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:50:31
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:50:31
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:50:31
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:50:31
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:50:31
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:50:31

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '6 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.9' F	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:51:10
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:51:10
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:51:10

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '7 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Sep 2020 12:52:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.8' F	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:52:05
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:52:05
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:52:05
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:52:05
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:52:05
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:52:05
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:52:05
	(b) (4)	

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:52:05
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:52:05
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:52:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	08 Sep 2020 12:52:05

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '08 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.8' F	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:19

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 17 (Day 17)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '09 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Sep 2020 16:35:50

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.1' F	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:35:50
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:35:50
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:35:50
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:35:50
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:35:50

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:35:50
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:35:50

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 18 (Day 18)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '10 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Sep 2020 16:36:26

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.6' F	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:36:26
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:36:26
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:36:26
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:36:26

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:36:26
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 19 (Day 19)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '11 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.9' F	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:38:43
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:38:43
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:38:43

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 20 (Day 20)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '12 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.9' F	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:39:49
	(b) (4)	

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:39:49

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 21 (Day 21)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[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 21SEP2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 01:45:10
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 21SEP2020. Please reconcile or clarify.' answered with 'Symptoms subsided' (Site from DM).	Alayna Wilder (b) (4)	09 Nov 2020 18:58:14
User opened query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 21SEP2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:52:27
User entered '13 Sep 2020'	Sharon Mathys (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '98'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered '97.3' F	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:31:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:03
User entered 'None (None)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:40:34

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:31:01

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:49
User entered '24 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	04 Sep 2020 17:26:56
User entered '22 Aug 2020'	Sharon Mathys (b) (4)	24 Aug 2020 14:09:33

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[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:49
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:09:33

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

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[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:49
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 15:26:41
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'COVID-19 diagnosis entered on the Adverse events form' (Site from System).	mayur ramesh (b) (4)	29 Aug 2020 18:03:25
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4)	
User entered 'Yes (Y)'	System	24 Aug 2020 14:09:33
	Sharon Mathys (b) (4)	24 Aug 2020 14:09:33
	(b) (4)	

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[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:49
User entered '24 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	04 Sep 2020 17:26:56
User entered '22 Aug 2020'	Sharon Mathys (b) (4)	24 Aug 2020 14:09:33

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Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

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[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:49
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:09:33

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Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:31:01

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:49
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:09:33

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[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 19:55:49
User entered 'No (N)' reason for change: New Information	Sharon Mathys (b) (4)	04 Sep 2020 17:26:30
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	24 Aug 2020 14:09:33

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:49
User entered empty; reason for change New Information	Sharon Mathys (b) (4)	04 Sep 2020 17:26:30
User entered 'Henry Ford Microbiology'	Sharon Mathys (b) (4)	24 Aug 2020 14:09:33

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Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:55:49
User entered empty; reason for change New Information	Sharon Mathys (b) (4)	04 Sep 2020 17:26:30
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	24 Aug 2020 14:09:33

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Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:09:33

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:31:01

Did the subject have Respiratory Rates $\geq$ 30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:31:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:31:01

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Folder: Covid-19 Assessment 24 Aug 2020

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[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Covid-19 Severity Assessment

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[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:36:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 11:36:02
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	27 Aug 2020 11:36:02
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:35:33
User entered empty.	Sharon Mathys (b) (4)	27 Aug 2020 11:35:33

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:31:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:31:01

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Folder: Covid-19 Assessment 24 Aug 2020

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[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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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)	10 Nov 2020 12:55:28
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:36:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 11:36:02
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	27 Aug 2020 11:36:02
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:35:33
User entered empty.	Sharon Mathys (b) (4)	27 Aug 2020 11:35:33

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:31:01

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Form: Covid-19 Severity Assessment

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:36:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 11:36:02
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	27 Aug 2020 11:36:02
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:35:33
User entered empty.	Sharon Mathys (b) (4)	27 Aug 2020 11:35:33

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:31:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:31:01

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:36:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 11:36:02
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	27 Aug 2020 11:36:02
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:35:33
User entered empty.	Sharon Mathys (b) (4)	27 Aug 2020 11:35:33

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:36:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 11:36:02
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	27 Aug 2020 11:36:02
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:35:33
User entered empty.	Sharon Mathys (b) (4)	27 Aug 2020 11:35:33

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:31:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Folder: Covid-19 Assessment 24 Aug 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:31:01

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Folder: Covid-19 Assessment 24 Aug 2020

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:31:01

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User closed query 'Per CDM: it appears ICU is recorded as NO but a date is present. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 05:29:56
Query 'Per CDM: it appears ICU is recorded as NO but a date is present. Please reconcile and update accordingly.' answered with 'Misunderstanding. Thought it was start and end of COV2 infection. Removed' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:28:09
User opened query 'Per CDM: it appears ICU is recorded as NO but a date is present. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:21:43
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:36:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 11:36:02
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:36:02
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:35:33
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:31:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	14 Sep 2020 18:27:38
User entered '22 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	27 Aug 2020 11:36:02
User entered empty.	Sharon Mathys (b) (4)	27 Aug 2020 11:35:33

US3522042

Folder: Covid-19 Assessment 24 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:31:01

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:35:33

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:31:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:31:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:23
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:31:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:23
User entered '26 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:31:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:31:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:25
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 18:04:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 18:04:37
User entered 'Yes (Y)' reason for change: Data Entry Error	mayur ramesh (b) (4)	29 Aug 2020 18:04:37
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 15:34:21
User entered empty.	Sharon Mathys (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:31:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:25
User entered '28 Aug 2020' reason for change: Data Entry Error	mayur ramesh (b) (4)	29 Aug 2020 18:04:37
User entered empty.	Sharon Mathys (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:31:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:31:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:28
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 17:35:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 17:35:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	31 Aug 2020 17:35:08
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 15:34:21
User entered empty.	Sharon Mathys (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:31:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:04:28
User entered '30 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	31 Aug 2020 17:35:08
User entered empty.	Sharon Mathys (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:31:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:31:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:09
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 16:14:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 16:14:35
User entered 'Yes (Y)' reason for change: New Information	Sharon Mathys (b) (4)	01 Sep 2020 16:14:35
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 15:34:21
User entered empty.	Sharon Mathys (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:31:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:09
User entered '1 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	01 Sep 2020 16:14:35
User entered empty.	Sharon Mathys (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:31:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:31:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:29
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 10:16:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 10:16:03
User entered 'Yes (Y)' reason for change: Data Entry Error	mayur ramesh (b) (4)	08 Sep 2020 10:16:03
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 15:34:21
User entered empty.	Sharon Mathys (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:31:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:06:29
User entered '06 Sep 2020' reason for change: Data Entry Error	mayur ramesh (b) (4)	08 Sep 2020 10:16:03
User entered empty.	(b) (4)	
	Sharon Mathys (b) (4)	26 Aug 2020 15:34:21
	(b) (4)	

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:31:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:31:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Sep 2020 16:41:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'waiting to enter until day 21' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 02:14:20
User opened query 'Data is required. Please complete.' (Site from System).	Sharon Mathys (b) (4)	08 Sep 2020 18:54:23
User entered empty.	(b) (4)	
	System	26 Aug 2020 15:34:21
	Sharon Mathys (b) (4)	26 Aug 2020 15:34:21
	(b) (4)	

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:31:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:08
User entered '13 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Sep 2020 16:41:01
User entered empty.	Sharon Mathys (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:31:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:31:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Sep 2020 16:41:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'waiting to enter until day 28' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 02:15:38
User opened query 'Data is required. Please complete.' (Site from System).	Sharon Mathys (b) (4)	08 Sep 2020 18:54:46
User entered empty.	(b) (4)	
	System	26 Aug 2020 15:34:21
	Sharon Mathys (b) (4)	26 Aug 2020 15:34:21
	(b) (4)	

US3522042

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:31:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:07:46
User entered '21 Sep 2020' reason for change: New Information	Sharon Mathys (b) (4)	22 Sep 2020 16:41:40
User entered empty.	Sharon Mathys (b) (4)	26 Aug 2020 15:34:21

US3522042

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:17
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:31:21

US3522042

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:17
User entered '24 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:31:21

US3522042

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:48:17
User entered 'Clinic (Clinic)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:31:21

US3522042

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	26 Aug 2020 15:31:21

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered '24 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User closed query 'Unable to locate time per source review. Please review and advise to time location in source.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 12:06:01
Query 'Unable to locate time per source review. Please review and advise to time location in source.' answered with 'Made it more clear in Source' (Site from CRA).	Sharon Mathys (b) (4)	17 Sep 2020 15:31:19
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:28
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User opened query 'Unable to locate time per source review. Please review and advise to time location in source.' (Site from CRA).	(b) (4), (b) (6)	10 Sep 2020 20:07:53
User entered '16:05'	Sharon Mathys (b) (4)	26 Aug 2020 15:33:18

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 16:05'	System	26 Aug 2020 15:33:18

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

Height (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 15:33:52
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 15:33:52
User entered '67' in reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:33:52
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 15:33:18
User entered empty.	Sharon Mathys (b) (4)	26 Aug 2020 15:33:18
DataPoint set to visible.	System	26 Aug 2020 15:31:21

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 15:33:52
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 15:33:52
User entered '178.2' lb reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Aug 2020 15:33:52
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 15:33:18
User entered empty.	Sharon Mathys (b) (4)	26 Aug 2020 15:33:18
DataPoint set to visible.	(b) (4) System	26 Aug 2020 15:31:21

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered '97.3' F	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered 'Oral (Oral)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered '60'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Aug 2020 15:33:18

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered '14'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Aug 2020 15:33:18

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered '129'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Aug 2020 15:33:18

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:23
User entered '93'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:33:18

US3522042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Aug 2020 15:33:18

US3522042

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:36
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:31:29

US3522042

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:36
User entered '24 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:31:29

US3522042

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:31:01

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:40
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:05

US3522042

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:31:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:08:40
User entered '24 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:34:05

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:26
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:41:53

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:08:26
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:41:53

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

[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 13:08:26
User entered 'Clinic (Clinic)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:41:53

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	22 Sep 2020 16:41:53

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:06
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:06
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:06
User entered '11:32'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:32'	System	22 Sep 2020 16:48:40

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

Height (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:06
User closed query 'Per CDM: Per CCG, data to be entered for "height and weight". Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:42:49
Query 'Per CDM: Per CCG, data to be entered for "height and weight". Please update accordingly. ' answered with 'was not measured at visit' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 15:09:12
User opened query 'Per CDM: Per CCG, data to be entered for "height and weight". Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:15:19
User entered missing code ND - Not Done.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40
DataPoint set to visible.	System	22 Sep 2020 16:41:53

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:06
User closed query 'Per CDM: Per CCG, data to be entered for "height and weight". Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:42:52
Query 'Per CDM: Per CCG, data to be entered for "height and weight". Please update accordingly. ' answered with 'was not measured at visit' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	06 Nov 2020 15:09:18
User opened query 'Per CDM: Per CCG, data to be entered for "height and weight". Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:15:26
User entered missing code ND - Not Done.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40
DataPoint set to visible.	System	22 Sep 2020 16:41:53

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:21
User entered '97.8' F	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:50
User entered 'Oral (Oral)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:51
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:54
User entered '55'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 16:48:40

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:09:59
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:27:54
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	22 Sep 2020 18:27:54
User entered '16' reason for change: New Information	Sharon Mathys (b) (4)	22 Sep 2020 18:27:54
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 16:48:40
User entered empty.	Sharon Mathys (b) (4)	22 Sep 2020 16:48:40

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 18:27:54
User entered empty.	System	22 Sep 2020 16:48:40

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:01
User entered '139'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 16:48:40

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:03
User entered '93'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:48:40

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 16:48:40

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:10
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:42:03

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:10
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:42:03

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:31:01

[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 13:10:26
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:51:53

US3522042

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:31:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:10:26
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 16:51:53

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:31:01

[Visit Date](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 01:45:25
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 01:45:22
Query 'Data is required. Please complete.' answered with 'Updated' (Site from System).	Alayna Wilder (b) (4)	09 Nov 2020 18:54:25
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 'Updated' (Site from DM).	Alayna Wilder (b) (4)	09 Nov 2020 18:54:17
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 18:53:55
DataPoint Un-verified.	Alayna Wilder (b) (4)	09 Nov 2020 18:53:55
User entered empty; reason for change Data Entry Error	Alayna Wilder (b) (4)	09 Nov 2020 18:53:55
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 04:51:05
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:14
User closed query 'Per CDM : Please confirm the purpose of this visit as none of the below checked forms are filled. If this Unscheduled Visit was populated in error, please remove the data and get all the pages pertaining to this visit inactivated. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 00:22:22
Query 'Per CDM : Please confirm the purpose of this visit as none of the below checked forms are filled. If this Unscheduled Visit was populated in error, please remove the data and get all the pages pertaining to this visit inactivated. Thank you.' answered with 'We were previously told to leave those pages blank to prevent duplicate data from the illness visit. Have been informed today to fill them out so there is now duplicate data. Please inform us if there is any change before you ping up queries.' (Site from DM).	Sharon Mathys (b) (4)	04 Sep 2020 17:25:52

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:31:01

[Visit Date](#)

Audit	User	Time (GMT)
User opened query 'Per CDM : Please confirm the purpose of this visit as none of the below checked forms are filled. If this Unscheduled Visit was populated in error, please remove the data and get all the pages pertaining to this visit inactivated. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 16:49:19
User entered '24 Aug 2020'	Sharon Mathys (b) (4)	28 Aug 2020 16:40:56

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:31:01

[Physical Exam](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Alayna Wilder (b) (4)	09 Nov 2020 18:53:55
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Alayna Wilder (b) (4)	09 Nov 2020 18:53:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:14
User entered '1'	Sharon Mathys (b) (4)	28 Aug 2020 16:40:56
	(b) (4)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:31:01

[Vital Signs](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Alayna Wilder (b) (4)	09 Nov 2020 18:53:55
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Alayna Wilder (b) (4)	09 Nov 2020 18:53:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:14
User entered '1'	Sharon Mathys (b) (4)	28 Aug 2020 16:40:56
	(b) (4)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:31:01

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Alayna Wilder (b) (4)	09 Nov 2020 18:53:55
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Alayna Wilder (b) (4)	09 Nov 2020 18:53:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:14
User entered '1'	Sharon Mathys (b) (4)	28 Aug 2020 16:40:56
	(b) (4)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:31:01

[Pregnancy Test](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:40
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:14
User entered '0'	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 16:40:56

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[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 01:45:32
Query 'Data is required. Please complete.' answered with 'cleared for inactivation' (Site from System).	Sharon Mathys (b) (4)	10 Nov 2020 14:20:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 14:20:34
	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 20:09:24
User entered 'Yes (Y)'	(b) (4)	
	Sharon Mathys (b) (4)	04 Sep 2020 17:24:29
	(b) (4)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:24
User entered '24 Aug 2020'	Sharon Mathys (b) (4)	04 Sep 2020 17:24:29
	(b) (4)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:11:55
	(b) (4), (b) (6)	
User closed query 'Unable to locate time per source review. Please review and advise to time location in source' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 13:11:53
Query 'Unable to locate time per source review. Please review and advise to time location in source' answered with 'Made clearer in source' (Site from CRA).	Sharon Mathys (b) (4)	17 Sep 2020 15:31:59
	(b) (4)	
User opened query 'Unable to locate time per source review. Please review and advise to time location in source' (Site from CRA).	(b) (4), (b) (6)	10 Sep 2020 20:09:34
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:26
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:24
User entered '16:05'	Sharon Mathys (b) (4)	04 Sep 2020 17:24:29
	(b) (4)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:20:34
User entered '24 Aug 2020 16:05'	System	04 Sep 2020 17:24:29

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:24
User entered '97.3' F	Sharon Mathys (b) (4)	04 Sep 2020 17:24:29
	(b) (4)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:24
User entered 'Oral (Oral)'	Sharon Mathys (b) (4)	04 Sep 2020 17:24:29
	(b) (4)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:24
User entered empty.	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 17:24:29

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:24
User entered '60'	Sharon Mathys (b) (4)	04 Sep 2020 17:24:29
	(b) (4)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:20:34
User entered 'bpm'	System	04 Sep 2020 17:24:29

US3522042

Folder: **Unscheduled 24 Aug 2020**

Form: **Vital Signs**

Generated On: **26 Nov 2020 09:31:01**

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

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:24
User entered '14'	Sharon Mathys (b) (4)	04 Sep 2020 17:24:29
	(b) (4)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:20:34
User entered 'breaths/min'	System	04 Sep 2020 17:24:29

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:24
User entered '129'	Sharon Mathys (b) (4)	04 Sep 2020 17:24:29
	(b) (4)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:20:34
User entered 'mmHg'	System	04 Sep 2020 17:24:29

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:20:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:24
User entered '93'	Sharon Mathys (b) (4)	04 Sep 2020 17:24:29
	(b) (4)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:20:34
User entered 'mmHg'	System	04 Sep 2020 17:24:29

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

Was the physical examination performed?

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:20:52
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	04 Sep 2020 17:24:41
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 16:45:14
Query 'Data is required. Please complete.' answered with 'told to leave blank' (Site from System).	Sharon Mathys (b) (4)	03 Sep 2020 14:57:36
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:57:29
User closed query 'Was the physical examination performed is No for this unscheduled visit. Please change to Yes or remove this unscheduled Physical Examination form.' (Site from System).	System	03 Sep 2020 14:57:29
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	03 Sep 2020 14:57:29
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:56:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 14:56:35
User opened query 'Was the physical examination performed is No for this unscheduled visit. Please change to Yes or remove this unscheduled Physical Examination form.' (Site from System).	System	03 Sep 2020 14:56:35
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	03 Sep 2020 14:56:35
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:56:27
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	03 Sep 2020 14:56:27
	(b) (4)	
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	28 Aug 2020 19:59:20
	(b) (4)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:20:52
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:38
User entered '24 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	04 Sep 2020 17:24:41
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	03 Sep 2020 14:56:27
	(b) (4)	
User entered '24 Aug 2020'	Sharon Mathys (b) (4)	28 Aug 2020 19:59:20
	(b) (4)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

[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 01:44:22
Query 'Data is required. Please complete.' answered with 'cleared for inactivation' (Site from System).	Sharon Mathys (b) (4)	10 Nov 2020 14:21:16
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 14:21:09
	Sharon Mathys (b) (4)	10 Nov 2020 14:21:09
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	10 Nov 2020 14:21:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 20:09:45
User entered 'Yes (Y)'	(b) (4)	
	Sharon Mathys (b) (4)	04 Sep 2020 17:24:58
	(b) (4)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:21:09
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:21:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:45
User entered '24 Aug 2020'	Sharon Mathys (b) (4)	04 Sep 2020 17:24:58
	(b) (4)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sharon Mathys (b) (4)	10 Nov 2020 14:21:09
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 14:21:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 20:09:45
User entered '16:15'	Sharon Mathys (b) (4)	04 Sep 2020 17:24:58
	(b) (4)	

US3522042

Folder: Unscheduled 24 Aug 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 14:21:09
User entered '24 Aug 2020 16:15'	System	04 Sep 2020 17:24:58

US3522042

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:31:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:54
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 13:51:07

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:20:59
User entered 'USA-US131-2020-mRNA-1273-P301000001'	System	24 Aug 2020 16:20:43
User entered 'New'	(b) (4), (b) (6)	24 Aug 2020 16:20:43

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Adverse event](#)

Audit	User	Time (GMT)
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)	23 Nov 2020 21:38:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 21:38:26
Data point term sent to Coder	System	23 Nov 2020 20:59:20
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4)	23 Nov 2020 20:59:01
' canceled (Site from System).		
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4)	23 Nov 2020 12:23:52
' (Site from System).		
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Per DM CLR: Please review and confirm if AE#2-7 were symptoms of this AE (COVID-19 INFECTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis, and remove duplicate data as appropriate. Update eCRF as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 07:59:04
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 11:59:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 11:59:52

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review and confirm if AE#2-7 were symptoms of this AE (COVID-19 INFECTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis, and remove duplicate data as appropriate. Update eCRF as appropriate. Otherwise, clarify.' answered with 'updated name to say symptomatic covid-19 per ecrf guideline. deactivating all other symptom lines' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 11:59:19
Data point term sent to Coder	System	30 Oct 2020 11:58:52
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 11:58:36
User entered 'Symptomatic COVID-19' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 11:58:36
User opened query 'Per DM CLR: Please review and confirm if AE#2-7 were symptoms of this AE (COVID-19 INFECTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis, and remove duplicate data as appropriate. Update eCRF as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:51:58
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:26:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:26:41
Data point term sent to Coder	System	24 Aug 2020 14:25:53
User entered 'COVID-19 Infection'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:30:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 14:30:43
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Aug 2020 14:30:43
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:25:38
User entered empty.	Sharon Mathys (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Per ETRTR: Please complete data entry in Illness Visit as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:37:34
Query 'Per ETRTR: Please complete data entry in Illness Visit as required, thanks.' answered with 'have been doing. entered in source, transferred initial on 8/26' (Site from CRA).	Sharon Mathys (b) (4) (b) (4)	27 Aug 2020 11:26:44
User opened query 'Per ETRTR: Please complete data entry in Illness Visit as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 15:50:20
User entered '22 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Aug 2020 14:30:57
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	24 Aug 2020 14:30:57
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Aug 2020 14:25:38
User entered '09:00'	Sharon Mathys (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 14:30:57
User entered '22 Aug 2020 09:00'	System	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	14 Sep 2020 18:33:01
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '30 Aug 2020' reason for change: New Information	Sharon Mathys (b) (4)	19 Sep 2020 21:27:09
User closed query 'PV Query: Please provide the event end date (resolution of symptoms), when available. Please leave query open until information is available.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide the event end date (resolution of symptoms), when available. Please leave query open until information is available.' answered with 'Symptom free earlier but negative saline test on day 7' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 22:11:25
Query 'PV Query: Please provide the event end date (resolution of symptoms), when available. Please leave query open until information is available.'	Sharon Mathys (b) (4)	14 Sep 2020 18:33:22
answered with 'Symptom free earlier but negative saline test on day 7' (Site from Safety).	(b) (4)	
User entered '31 Aug 2020' reason for change: New Information	Sharon Mathys (b) (4)	14 Sep 2020 18:33:01
User opened query 'PV Query: Please provide the event end date (resolution of symptoms), when available. Please leave query open until information is available.' (Site from Safety).	(b) (4)	
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 13:53:05
	Sharon Mathys (b) (4)	24 Aug 2020 14:25:38
	(b) (4)	

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Per ETRTR: Please provide the event end date, when available.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:37:41
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	31 Aug 2020 12:49:26
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'ongoing but improving ' (Site from Safety).	mayur ramesh (b) (4)	29 Aug 2020 17:51:09
Query 'Per ETRTR: Please provide the event end date, when available.' answered with 'ongoing' (Site from CRA).	mayur ramesh (b) (4)	29 Aug 2020 17:50:32
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 18:10:09
User opened query 'Per ETRTR: Please provide the event end date, when available.' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 15:41:32
User entered empty.	Sharon Mathys (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Per CDM: please confirm if this event meets SAE criteria and update accordingly' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 05:17:06
Query 'Per CDM: please confirm if this event meets SAE criteria and update accordingly' answered with 'does not meet serious criteria' (Site from DM).	Sharon Mathys (b) (4)	16 Oct 2020 15:02:59
User opened query 'Per CDM: please confirm if this event meets SAE criteria and update accordingly' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 00:11:34
User entered 'No (N)'	Sharon Mathys (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:59:08
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	14 Sep 2020 18:33:01
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	14 Sep 2020 13:54:26
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	14 Sep 2020 13:52:42
User closed query 'PV Query: Relationship to investigational product and study procedure has been reported as Not applicable. Per protocol, appropriate response would be either Related or Not related. Please updated causality assessment accordingly. ' (Site from Safety).	(b) (4), (b) (6)	31 Aug 2020 12:49:32
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	29 Aug 2020 17:54:10
Query 'PV Query: Relationship to investigational product and study procedure has been reported as Not applicable. Per protocol, appropriate response would be either Related or Not related. Please updated causality assessment accordingly. ' answered with 'ok' (Site from Safety).	Sharon Mathys (b) (4)	28 Aug 2020 13:52:18
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	28 Aug 2020 13:50:52
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	28 Aug 2020 13:50:52

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	28 Aug 2020 13:50:52
User opened query 'PV Query: Relationship to investigational product and study procedure has been reported as Not applicable. Per protocol, appropriate response would be either Related or Not related. Please updated causality assessment accordingly. ' (Site from Safety).	(b) (4)	
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).	(b) (4), (b) (6)	27 Aug 2020 18:09:45
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).		
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Aug 2020 14:31:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 14:30:43
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	24 Aug 2020 14:30:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Aug 2020 14:30:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	24 Aug 2020 14:25:38
	Sharon Mathys (b) (4)	24 Aug 2020 14:25:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	28 Aug 2020 13:51:13
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Aug 2020 14:31:25
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:30:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 14:30:43
User entered 'Related (RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Aug 2020 14:30:43
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:25:38
User entered empty.	Sharon Mathys (b) (4)	24 Aug 2020 14:25:38

US3522042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	16 Oct 2020 15:04:31
User entered 'None (NONE)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 19:59:08
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 05:14:17
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please consider updating action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 22:11:35
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please consider updating action taken to withdrawn.' answered with 'Updated action to withdrawn' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:35:43
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'COV2 positive diagnosis is not related to IP or to study procedure but is a reason to withdraw IP' (Site from System).	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:35:32
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 18:33:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 18:33:01
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	14 Sep 2020 18:33:01
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:33:01

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 13:54:26
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	14 Sep 2020 13:54:26
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	14 Sep 2020 13:54:26
User entered empty; reason for change Data Entry Error	Jelena Verkler (b) (4)	14 Sep 2020 13:54:26
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	14 Sep 2020 13:52:42
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Jelena Verkler (b) (4)	14 Sep 2020 13:52:42
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please consider updating action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 13:53:52
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	mayur ramesh (b) (4)	29 Aug 2020 17:54:10
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 11:34:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 11:34:29
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	27 Aug 2020 11:34:29
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:31:25
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	24 Aug 2020 14:31:25
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:30:43

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 14:30:43
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Aug 2020 14:30:43
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:25:38
User entered empty.	Sharon Mathys (b) (4)	24 Aug 2020 14:25:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #3 recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 11:46:42
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #3 recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	09 Nov 2020 14:48:34
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	09 Nov 2020 14:48:29
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #3 recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:32:12
User entered '1'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4)	09 Nov 2020 14:48:29
User entered '0'	Sharon Mathys (b) (4)	24 Aug 2020 14:25:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 22:11:43
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Recovered from infection. Still finishing illness to go to convalescence visit.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:36:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:33:01
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 13:53:25
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	31 Aug 2020 12:49:45
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'expected to resolve' (Site from Safety).	mayur ramesh (b) (4) (b) (4)	29 Aug 2020 17:52:48
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 18:10:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Aug 2020 14:25:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:13:42
User closed query 'Per DM CLR: SAE Narrative = TOOK TYLENOL 650 MG ONCE, 24 TEMP 98, MILD BODY ACHES, TYLENOL 650 MG ONCE IN MORNING. However, CM indication is FEVER at CM eCRF. Please review and verify if the same medication was given for this AE. If yes, add this AE to the CM indication so there will be an appropriate match. Update eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 07:59:16
Query 'Per DM CLR: SAE Narrative = TOOK TYLENOL 650 MG ONCE, 24 TEMP 98, MILD BODY ACHES, TYLENOL 650 MG ONCE IN MORNING. However, CM indication is FEVER at CM eCRF. Please review and verify if the same medication was given for this AE. If yes, add this AE to the CM indication so there will be an appropriate match. Update eCRF as appropriate. Otherwise, clarify. ' answered with 'updated concom med to state it was for symptomatic covid-19 as it was for a fever on one day and body aches the next, but both were due to covid-19' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 11:58:22
User opened query 'Per DM CLR: SAE Narrative = TOOK TYLENOL 650 MG ONCE, 24 TEMP 98, MILD BODY ACHES, TYLENOL 650 MG ONCE IN MORNING. However, CM indication is FEVER at CM eCRF. Please review and verify if the same medication was given for this AE. If yes, add this AE to the CM indication so there will be an appropriate match. Update eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:51:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Participant CONTACTED US ON 8/24/2020 TO TELL US HE HAD SYMPTOMS AND TESTED POSITIVE FOR COVID-19 ON 8/22/2020 AFTER PREVIOUSLY ATTENDING A FAMILY GATHERING WHICH LATER HAD MULTIPLE MEMBERS TEST POSITIVE. INITIAL SYMPTOMS ON THE 22ND WAS 100.9 F, MILD CHILLS, MILD HEADACHE, MODERATE LOSS OF SMELL, MILD COUGH, MILD BODY ACHES. NO MEDS TAKEN. 23RD TEMP WAS 99, TOOK TYLENOL 650 MG ONCE, 24 TEMP 98, MILD BODY ACHES, TYLENOL 650 MG ONCE IN MORNING. IN AFTERNOON WENT TO ILLNESS VISIT AT CLINIC SO DAY 1 FOR STUDY OBSERVATION IS DAY 3 OF INFECTION. ILLNESS VISIT D1 SWAB SENT TO VIRACOR AND TESTED POSITIVE. DAY 7 SALIVA FROM 30 AUG 2020 TESTED NEGATIVE' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	16 Oct 2020 15:06:14
User entered 'PARTICIPANT CONTACTED US ON 8/24/2020 TO TELL US HE HAD SYMPTOMS AND TESTED POSITIVE FOR COVID-19 ON 8/22/2020 AFTER PREVIOUSLY ATTENDING A FAMILY GATHERING WHICH LATER HAD MULTIPLE MEMBERS TEST POSITIVE. INITIAL SYMPTOMS ON THE 22ND WAS 100.9 F, MILD CHILLS, MILD HEADACHE, MODERATE LOSS OF SMELL, MILD COUGH, MILD BODY ACHES. NO MEDS TAKEN. 23RD TEMP WAS 99, TOOK TYLENOL 650 MG ONCE, 24 TEMP 98, MILD BODY ACHES, TYLENOL 650 MG ONCE IN MORNING. IN AFTERNOON WENT TO ILLNESS VISIT AT CLINIC SO DAY 1 FOR STUDY OBSERVATION IS DAY 3 OF INFECTION. ILLNESS VISIT D1 SWAB SENT TO VIRACOR AND TESTED POSITIVE. DAY 7 SALIVA FROM 30 AUG 2020 TESTED NEGATIVE' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	16 Oct 2020 15:05:02
User closed query 'PV Query: Please provide the date of negative saliva test.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	20 Sep 2020 21:12:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the date of negative saliva test.' answered with '30 AUG 2020 test was negative' (Site from Safety).	Sharon Mathys (b) (4)	19 Sep 2020 21:26:36
User entered 'PARTICIPANT CONTACTED US ON 8/24/2020 TO TELL US HE HAD SYMPTOMS AND TESTED POSITIVE FOR COVID-19 ON 8/22/2020 AFTER PREVIOUSLY ATTENDING A FAMILY GATHERING WHICH LATER HAD MULTIPLE MEMBERS TEST POSITIVE. INITIAL SYMPTOMS ON THE 22ND WAS 100.9 F, MILD CHILLS, MILD HEADACHE, MODERATE LOSS OF SMELL, MILD COUGH, MILD BODY ACHES. NO MEDS TAKEN. 23RD TEMP WAS 99, TOOK TYLENOL 650 MG ONCE, 24 TEMP 98, MILD BODY ACHES, TYLENOL 650 MG ONCE IN MORNING. IN AFTERNOON WENT TO ILLNESS VISIT AT CLINIC SO DAY 1 FOR STUDY OBSERVATION IS DAY 3 OF INFECTION. ILLNESS VISIT D1 SWAB SENT TO VIRACOR AND TESTED POSITIVE. Day 7 saliva from 30 Aug 2020 tested negative' reason for change: New Information	Sharon Mathys (b) (4)	19 Sep 2020 21:26:24
User opened query 'PV Query: Please provide the date of negative saliva test.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 15:01:13
User closed query 'PV Query: Please confirm if the patient had any known exposure to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 22:11:52
User closed query 'PV Query: Thank you for confirming that seasonal allergies is considered medical history. Please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 22:11:47
Query 'PV Query: Please confirm if the patient had any known exposure to COVID-19.' answered with 'Added to the narrative about the family gathering.' (Site from Safety).	Sharon Mathys (b) (4)	14 Sep 2020 18:41:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT CONTACTED US ON 8/24/2020 TO TELL US HE HAD SYMPTOMS AND TESTED POSITIVE FOR COVID-19 ON 8/22/2020 after previously attending a family gathering which later had multiple members test positive. INITIAL SYMPTOMS ON THE 22ND WAS 100.9 F, MILD CHILLS, MILD HEADACHE, MODERATE LOSS OF SMELL, MILD COUGH, MILD BODY ACHES. NO MEDS TAKEN. 23RD TEMP WAS 99, TOOK TYLENOL 650 MG ONCE, 24 TEMP 98, MILD BODY ACHES, TYLENOL 650 MG ONCE IN MORNING. IN AFTERNOON WENT TO ILLNESS VISIT AT CLINIC SO DAY 1 FOR STUDY OBSERVATION IS DAY 3 OF INFECTION. ILLNESS VISIT D1 SWAB SENT TO VIRACOR AND TESTED POSITIVE.' reason for change: New Information Query 'PV Query: Thank you for confirming that seasonal allergies is considered medical history. Please add to MH eCRF.' answered with 'Added' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:41:35
User closed query 'Per ETRTR: COVID + Narrative should describe clinical course of events, dates, times, treatments (include in ConMeds CRF) and any other assessments which help explain the event. Please add as required, thanks.' (Site from CRA).	Sharon Mathys (b) (4) (b) (4)	14 Sep 2020 18:40:08
User opened query 'PV Query: Please confirm if the patient had any known exposure to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 17:37:48
User opened query 'PV Query: Thank you for confirming that seasonal allergies is considered medical history. Please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 13:54:04
User closed query 'PV Query: Please provide results of additional SARS-CoV-2 PCR tests (if and when performed), including Day 1 results.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 13:53:36
	(b) (4), (b) (6)	31 Aug 2020 12:50:06

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	31 Aug 2020 12:50:02
User closed query 'PV Query: Please confirm if hypertension and seasonal allergies were part of subject's medical history or were considered as AEs. Please report them accordingly in EDC.' (Site from Safety).	(b) (4), (b) (6)	31 Aug 2020 12:49:55
User closed query 'PV Query: Please add subject's medical history (prior to Day 1) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	31 Aug 2020 12:49:51
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'no treatment ' (Site from Safety).	mayur ramesh (b) (4)	29 Aug 2020 17:54:03
Query 'PV Query: Please confirm if hypertension and seasonal allergies were part of subject's medical history or were considered as AEs. Please report them accordingly in EDC.' answered with 'medical history' (Site from Safety).	mayur ramesh (b) (4)	29 Aug 2020 17:53:33
Query 'Per ETRTR: COVID + Narrative should describe clinical course of events, dates, times, treatments (include in ConMeds CRF) and any other assessments which help explain the event. Please add as required, thanks.' answered with 'completed' (Site from CRA).	mayur ramesh (b) (4)	29 Aug 2020 17:53:08
Query 'PV Query: Please provide results of additional SARS-CoV-2 PCR tests (if and when performed), including Day 1 results.' answered with 'ok' (Site from Safety).	Sharon Mathys (b) (4)	28 Aug 2020 15:58:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:01

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT CONTACTED US ON 8/24/2020 TO TELL US HE HAD SYMPTOMS AND TESTED POSITIVE FOR COVID-19 ON 8/22/2020. INITIAL SYMPTOMS ON THE 22ND WAS 100.9 F, MILD CHILLS, MILD HEADACHE, MODERATE LOSS OF SMELL, MILD COUGH, MILD BODY ACHES. NO MEDS TAKEN. 23RD TEMP WAS 99, TOOK TYLENOL 650 MG ONCE, 24 TEMP 98, MILD BODY ACHES, TYLENOL 650 MG ONCE IN MORNING. IN AFTERNOON WENT TO ILLNESS VISIT AT CLINIC SO DAY 1 FOR STUDY OBSERVATION IS DAY 3 OF INFECTION. Illness Visit D1 swab sent to Viracor and tested positive.' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 15:58:10
Query 'PV Query: Please add subject's medical history (prior to Day 1) to medical history eCRF. If none, please state so.' answered with 'none to add' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 13:06:00
User opened query 'PV Query: Please provide results of additional SARS-CoV-2 PCR tests (if and when performed), including Day 1 results.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	27 Aug 2020 18:15:13
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	27 Aug 2020 18:13:46
User opened query 'PV Query: Please confirm if hypertension and seasonal allergies were part of subject's medical history or were considered as AEs. Please report them accordingly in EDC.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	27 Aug 2020 18:08:49
User opened query 'PV Query: Please add subject's medical history (prior to Day 1) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	27 Aug 2020 18:08:29

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Participant contacted us on 8/24/2020 to tell us he had symptoms and tested positive for Covid-19 on 8/22/2020. Initial symptoms on the 22nd was 100.9 F, mild chills, mild headache, moderate loss of smell, mild cough, mild body aches. No meds taken. 23rd temp was 99, took Tylenol 650 mg once, 24 temp 98, mild body aches, Tylenol 650 mg once in morning. in afternoon went to illness visit at clinic so day 1 for study observation is day 3 of infection.' reason for change: New Information	Sharon Mathys (b) (4)	27 Aug 2020 11:34:29
User opened query 'Per ETRTR: COVID + Narrative should describe clinical course of events, dates, times, treatments (include in ConMeds CRF) and any other assessments which help explain the event. Please add as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 15:44:36
User entered empty.	Sharon Mathys (b) (4)	24 Aug 2020 14:25:38

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Folder: Adverse Events

Form: Adverse Events (1)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	24 Aug 2020 14:25:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:25:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:31:01

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:07
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:46:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 13:49:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 13:49:11
Data point term sent to Coder	System	07 Aug 2020 13:48:01
User entered 'hydrochlorothiazide'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered 'hypertension'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered '12.5'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered 'mg (mg)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered 'once daily (QD)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered 'Oral (ORAL)'	Alandra White (b) (4)	07 Aug 2020 13:47:25

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:25:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Jelena Verkler (b) (4)	10 Aug 2020 16:19:41
answered with 'All concomitant medications are recorded for this subject.' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 14:57:26
User entered 'Un UNK 2012'	Alandra White (b) (4)	07 Aug 2020 13:47:25
	(b) (4)	

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered '0'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:16
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:47:25

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 13:47:25

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 13:47:25

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 13:47:25

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 13:51:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 13:51:16
Data point term sent to Coder	System	07 Aug 2020 13:49:01
User entered 'loratadine'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered 'seasonal allergies'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered '10'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered 'mg (mg)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered 'once daily (QD)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered 'Oral (ORAL)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered '1'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered empty.	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:30
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 13:48:29

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 11:58:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 11:58:52
Data point term sent to Coder Coding entries removed.	System Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 11:57:51 30 Oct 2020 11:57:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 11:56:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 11:56:51
Data point term sent to Coder Coding entries removed.	System Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 11:55:50 30 Oct 2020 11:54:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:27:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:27:43
Data point term sent to Coder User entered 'Tylenol'	System Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:50 26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User closed query 'Per DM CLR: Prophylaxis = YES. Please review response for this indication as there is an AE recorded that matches this medication and used within the same timeframe. Please correct response to "No" in prophylaxis field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 11:26:53
Query 'Per DM CLR: Prophylaxis = YES. Please review response for this indication as there is an AE recorded that matches this medication and used within the same timeframe. Please correct response to "No" in prophylaxis field as appropriate. ' answered with 'updated' (Site from DM).	Jelena Verkler (b) (4) (b) (4)	06 Oct 2020 16:29:48
User entered 'No (N)' reason for change: Data Entry Error	Jelena Verkler (b) (4) (b) (4)	06 Oct 2020 16:29:02
User opened query 'Per DM CLR: Prophylaxis = YES. Please review response for this indication as there is an AE recorded that matches this medication and used within the same timeframe. Please correct response to "No" in prophylaxis field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 14:21:10
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered 'Symptomatic COVID-19' reason for change: Data Entry Error	Sharon Mathys (b) (4)	30 Oct 2020 11:57:25
User entered 'FEVER/ Body Aches' reason for change: Data Entry Error	Sharon Mathys (b) (4)	30 Oct 2020 11:54:52
User entered 'Fever'	Sharon Mathys (b) (4)	26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered '650'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered 'once daily (QD)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered '23 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered '0'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User entered '24 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:27
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Fever in eDiary within this timeframe and AE indicates this condition is an Unsolicited event. Review response if this should be updated to "No" as appropriate.' (Site from DM). Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Fever in eDiary within this timeframe and AE indicates this condition is an Unsolicited event. Review response if this should be updated to "No" as appropriate.' answered with 'updated' (Site from DM). User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6) Jelena Verkler (b) (4) (b) (4) Jelena Verkler (b) (4) (b) (4)	07 Oct 2020 12:24:34 06 Oct 2020 16:29:54 06 Oct 2020 16:29:09
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Fever in eDiary within this timeframe and AE indicates this condition is an Unsolicited event. Review response if this should be updated to "No" as appropriate.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) Sharon Mathys (b) (4) (b) (4)	03 Oct 2020 14:21:40 26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 15:26:18

US3522042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:31:01

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	07 Aug 2020 13:44:52

US3522042

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:31:01

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 15:55:59

US3522042

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:31:01

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'Due to SARS-COV-2 (COVID)'	Sharon Mathys (b) (4) (b) (4)	01 Sep 2020 15:55:59

US3522042

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:31:01

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)	01 Sep 2020 15:55:59

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'USA-US131-2020-MRNA-1273-P301000001'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Marcus'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Kilgore'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Zervos'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)	System	14 Sep 2020 21:45:56
(b) (6)		
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '2799 West Grand Blvd'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Detroit'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'MI'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Michigan'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '48202'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:13:21
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:18:03
Un-reviewed for Safety.	System	15 Sep 2020 22:12:16
User entered 'US' (non-conformant).	System	15 Sep 2020 22:12:16
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	03 Sep 2020 14:53:15
Un-reviewed for Safety.	System	31 Aug 2020 12:52:28
User entered 'US' (non-conformant).	System	31 Aug 2020 12:52:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '01' reason for change: Data Entry Error	mayur ramesh (b) (4)	29 Aug 2020 17:44:02
User entered 'US' (non-conformant).	Sharon Mathys (b) (4)	26 Aug 2020 19:19:59
User entered 'U.' (non-conformant).	Sharon Mathys (b) (4)	26 Aug 2020 19:19:06
User entered 'US' (non-conformant).	System	24 Aug 2020 16:23:52

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Sep 2020 21:13:32
User entered '3'	System	15 Sep 2020 22:12:16
User entered '2'	System	31 Aug 2020 12:52:28
User entered '1'	System	24 Aug 2020 16:23:52

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'USA-US131-2020-MRNA-1273-P301000001'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Marcus'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Kilgore'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Zervos'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)	System	14 Sep 2020 21:45:56
(b) (6)		
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '2799 West Grand Blvd'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Detroit'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'MI'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Michigan'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '48202'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:13:21
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:18:03
Un-reviewed for Safety.	System	15 Sep 2020 22:12:16
User entered 'US' (non-conformant).	System	15 Sep 2020 22:12:16
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	03 Sep 2020 14:53:15
Un-reviewed for Safety.	System	31 Aug 2020 12:52:28
User entered 'US' (non-conformant).	System	31 Aug 2020 12:52:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '01' reason for change: Data Entry Error	mayur ramesh (b) (4)	29 Aug 2020 17:44:02
User entered 'US' (non-conformant).	Sharon Mathys (b) (4)	26 Aug 2020 19:19:59
User entered 'U.' (non-conformant).	Sharon Mathys (b) (4)	26 Aug 2020 19:19:06
User entered 'US' (non-conformant).	System	24 Aug 2020 16:23:52

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Sep 2020 21:13:32
User entered '3'	System	15 Sep 2020 22:12:16
User entered '2'	System	31 Aug 2020 12:52:28
User entered '1'	System	24 Aug 2020 16:23:52

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:31:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
User entered '24/Aug/2020 12:23'	System	24 Aug 2020 16:23:52

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:31:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '1'	(b) (4), (b) (6)	24 Aug 2020 16:23:52

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'USA-US131-2020-MRNA-1273-P301000001'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Marcus'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Kilgore'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Zervos'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)	System	14 Sep 2020 21:45:56
(b) (6)		
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '2799 West Grand Blvd'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Detroit'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'MI'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Michigan'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '48202'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:13:21
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:18:03
Un-reviewed for Safety.	System	15 Sep 2020 22:12:16
User entered 'US' (non-conformant).	System	15 Sep 2020 22:12:16
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	03 Sep 2020 14:53:15
Un-reviewed for Safety.	System	31 Aug 2020 12:52:28
User entered 'US' (non-conformant).	System	31 Aug 2020 12:52:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '01' reason for change: Data Entry Error	mayur ramesh (b) (4)	29 Aug 2020 17:44:02
User entered 'US' (non-conformant).	Sharon Mathys (b) (4)	26 Aug 2020 19:19:59
User entered 'U.' (non-conformant).	Sharon Mathys (b) (4)	26 Aug 2020 19:19:06
User entered 'US' (non-conformant).	System	24 Aug 2020 16:23:52

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Sep 2020 21:13:32
User entered '3'	System	15 Sep 2020 22:12:16
User entered '2'	System	31 Aug 2020 12:52:28
User entered '1'	System	24 Aug 2020 16:23:52

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:31:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
User entered '31/Aug/2020 08:52'	System	31 Aug 2020 12:52:28

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:31:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
User entered '1'	(b) (4), (b) (6)	31 Aug 2020 12:52:28

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'USA-US131-2020-MRNA-1273-P301000001'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Marcus'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Kilgore'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Zervos'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)	System	14 Sep 2020 21:45:56
(b) (6)		
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '2799 West Grand Blvd'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Detroit'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'MI'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Michigan'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '48202'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:13:21
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:18:03
Un-reviewed for Safety.	System	15 Sep 2020 22:12:16
User entered 'US' (non-conformant).	System	15 Sep 2020 22:12:16
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	03 Sep 2020 14:53:15
Un-reviewed for Safety.	System	31 Aug 2020 12:52:28
User entered 'US' (non-conformant).	System	31 Aug 2020 12:52:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '01' reason for change: Data Entry Error	mayur ramesh (b) (4)	29 Aug 2020 17:44:02
User entered 'US' (non-conformant).	Sharon Mathys (b) (4)	26 Aug 2020 19:19:59
User entered 'U.' (non-conformant).	Sharon Mathys (b) (4)	26 Aug 2020 19:19:06
User entered 'US' (non-conformant).	System	24 Aug 2020 16:23:52

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Sep 2020 21:13:32
User entered '3'	System	15 Sep 2020 22:12:16
User entered '2'	System	31 Aug 2020 12:52:28
User entered '1'	System	24 Aug 2020 16:23:52

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:31:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
User entered '15/Sep/2020 18:12'	System	15 Sep 2020 22:12:16

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:31:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:13:21
User entered '1'	(b) (4), (b) (6)	15 Sep 2020 22:12:16

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'USA-US131-2020-MRNA-1273-P301000001'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 16:23:45
User entered 'No (N)'	System	24 Aug 2020 16:20:43

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Marcus'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'Kilgore'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Zervos'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)	System	14 Sep 2020 21:45:56
(b) (6)		
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '2799 West Grand Blvd'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Detroit'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered 'MI'	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered 'Michigan'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:45:56
Amendment Manager: User entered (b) (6)	System	14 Sep 2020 21:45:56
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '48202'	Sharon Mathys (b) (4)	26 Aug 2020 19:18:46
	(b) (4)	

US3522042

Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:13:21
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:18:03
Un-reviewed for Safety.	System	15 Sep 2020 22:12:16
User entered 'US' (non-conformant).	System	15 Sep 2020 22:12:16
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 22:12:05
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	03 Sep 2020 14:53:15
Un-reviewed for Safety.	System	31 Aug 2020 12:52:28
User entered 'US' (non-conformant).	System	31 Aug 2020 12:52:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 12:52:16
User entered '01' reason for change: Data Entry Error	mayur ramesh (b) (4)	29 Aug 2020 17:44:02
User entered 'US' (non-conformant).	Sharon Mathys (b) (4)	26 Aug 2020 19:19:59
User entered 'U.' (non-conformant).	Sharon Mathys (b) (4)	26 Aug 2020 19:19:06
User entered 'US' (non-conformant).	System	24 Aug 2020 16:23:52

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Sep 2020 21:13:32
User entered '3'	System	15 Sep 2020 22:12:16
User entered '2'	System	31 Aug 2020 12:52:28
User entered '1'	System	24 Aug 2020 16:23:52

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Form: Safety Report Form (4)

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[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
User entered '20/Sep/2020 17:13'	System	20 Sep 2020 21:13:32

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Folder: SAE USA-US131-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:31:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 13:14:00
User entered '1'	(b) (4), (b) (6)	20 Sep 2020 21:13:32