

US3742253 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:12:49

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US3742253

Form: Participant Creation

Generated On: 26 Nov 2020 11:12:49

[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 11:12:49

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 SEP 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 11:12:49

Date of Birth (MMM yyyy)	(b) (6) 1976
Age	44
Age Units	YEARS
Age (Derived)	44
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 11:12:49

Date of Informed Consent (<i>dd MMM yyyy</i>)	04 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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 11:12:49

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:12:49

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

Condition	VITILIGO
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
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)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

Condition	ALLERGY TO PENICILLIN
Start date (dd MMM yyyy)	UN UNK 1976
Start date completely unknown	False
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)	(b) (6) 1976
Start Year (derived)	1976
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	04 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:05 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 10:05
Height (<i>xxx.x</i>)	67.0 in
Weight (<i>xxx.x</i>)	167.5 lb
BMI (<i>xxx.x</i>)	26.28906 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 11:12:49

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: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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	True
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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 SEP 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 11:12:49

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 111756

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:49

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 11:12:49

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)	4 SEP 2020
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 10:05
Temperature (xxx.x)	098.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	055 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	088 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 11:12:49

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)	4 SEP 2020
Time of assessment (00:00-23:59)	11:38 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 11:38
Temperature (xxx.x)	97.4 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	055 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	089 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 SEP 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: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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)	4 SEP 2020
What was the treatment time? (00:00-23:59)	11:06 (24 HR)
Treatment Date and Time (derived)	4 SEP 2020 11:06
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 11:12:49

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

4 SEP 2020

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

10:26 (24 HR)

Collection date and time (derived)

4 SEP 2020 10:26

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:12:49

Collection date (<i>dd MMM yyyy</i>)			4 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:29	4 SEP 2020 10:29
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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 11:12:49

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 11:38

PC Open Date & Time

04 SEP 2020 11:26

PC Close Date & Time

04 SEP 2020 13:56

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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	04 SEP 2020 22:40
PC Open Date & Time	04 SEP 2020 14:51
PC Close Date & Time	05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 21:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

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

97.8 °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

06 SEP 2020 12:26

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

08 SEP 2020 05:53

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 12:01

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 21:52

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

11 SEP 2020 06:04

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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

04 SEP 2020 11:37

PC Open Date & Time

04 SEP 2020 11:26

PC Close Date & Time

04 SEP 2020 13:56

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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

04 SEP 2020 22:41

PC Open Date & Time

04 SEP 2020 14:51

PC Close Date & Time

05 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

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

05 SEP 2020 21:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

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

06 SEP 2020 12:26

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

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

08 SEP 2020 05:53

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

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

08 SEP 2020 12:02

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

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

09 SEP 2020 21:52

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

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

11 SEP 2020 06:04

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 11:36
PC Open Date & Time	04 SEP 2020 11:26
PC Close Date & Time	04 SEP 2020 13:56

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 22:41
PC Open Date & Time	04 SEP 2020 14:51
PC Close Date & Time	05 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

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 ☒

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

Yes ☐	
PC Time stamp	05 SEP 2020 21:03
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

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 ☒

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

Yes ☐	
PC Time stamp	06 SEP 2020 12:27
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

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 ☒

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

Yes ☐	
PC Time stamp	08 SEP 2020 05:54
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

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 ☒

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

Yes ☐	
PC Time stamp	08 SEP 2020 12:02
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

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 ☒

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

Yes ☐	
PC Time stamp	09 SEP 2020 21:52
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

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 ☒

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

Yes ☐	
PC Time stamp	11 SEP 2020 06:05
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3742253

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742253

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742253

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742253

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742253

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742253

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742253

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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	

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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	

US3742253

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

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.

US3742253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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? _____

US3742253

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3742253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:12:49

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		

US3742253

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742253

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

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

PARTICIPANT IN
CONVALESCENT PERIOD.

If Contact Not Made, please provide Comments

US3742253

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742253

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

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

PARTICIPANT IN
CONVALESCENT PERIOD.

If Contact Not Made, please provide Comments

US3742253

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742253

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

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

PARTICIPANT IN
CONVALESCENT PERIOD.

If Contact Not Made, please provide Comments

US3742253

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742253

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3742253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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)	

US3742253

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 OCT 2020

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

US3742253

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

30 OCT 2020

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

11:54 (24 HR)

Collection date and time (derived)

30 OCT 2020 11:54

US3742253

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Date and time of submission	06 NOV 2020 14:59:15
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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	11 NOV 2020 22:29:21
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

18 NOV 2020 05:51:22

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

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19 AUG 2021 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

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13 JAN 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

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23 JAN 2022 00:01

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27 JAN 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

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03 FEB 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

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10 FEB 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

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

Date and time of submission

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US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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13 MAR 2022 00:01

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17 MAR 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

Date and time of submission

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20 MAR 2022 00:01

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24 MAR 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 MAR 2022 00:01

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31 MAR 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

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07 APR 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

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

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14 APR 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

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19 MAY 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

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02 JUN 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

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09 JUN 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

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21 JUL 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

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28 JUL 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

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31 JUL 2022 00:01

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04 AUG 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

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07 AUG 2022 00:01

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11 AUG 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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14 AUG 2022 00:01

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18 AUG 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

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21 AUG 2022 00:01

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25 AUG 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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28 AUG 2022 00:01

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01 SEP 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

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08 SEP 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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15 SEP 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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22 SEP 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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25 SEP 2022 00:01

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29 SEP 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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02 OCT 2022 00:01

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06 OCT 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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09 OCT 2022 00:01

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13 OCT 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

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16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3742253

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742253

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742253

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

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

US3742253

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:12:49

Date of Contact	25 SEP 2020
Time of Contact	08:48
Date and Time of Contact (derived)	25 SEP 2020 08:48
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 ☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	301 of 1958	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	21 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	305 of 1958	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	25 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	098.6 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)	309 of 1958	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	26 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	313 of 1958	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	27 OCT 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)	317 of 1958	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	28 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.0 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)	321 of 1958	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	29 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.0 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)	325 of 1958	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	30 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)	329 of 1958	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	01 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	96.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	333 of 1958	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	02 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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)	337 of 1958	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	03 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	341 of 1958	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	04 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.0 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)	345 of 1958	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	05 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	94.2 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)	349 of 1958	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	06 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	353 of 1958	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	07 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.2 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)	357 of 1958	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	08 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.0 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)	361 of 1958	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

	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	☐

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:12:49

Date of Visit	25 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Date of Test	25 SEP 2020
Type of Test Performed	Nasopharyngeal Swab ☐ Nasal Swab ☒ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	1

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

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:

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

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 _____

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

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

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:12:49

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 11:12:49

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	27 SEP 2020
Day 5	Yes	29 SEP 2020
Day 7	Yes	01 OCT 2020
Day 9	Yes	03 OCT 2020
Day 14	Yes	08 OCT 2020
Day 21	Yes	15 OCT 2020
Day 28	NA (COVID-19 Negative)	

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection

Generated On: 26 Nov 2020 11:12:49

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3742253

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	25 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	25 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:00 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 15:00
Height (<i>xxx.x</i>)	059 in
Weight (<i>xxx.x</i>)	171.6 lb
Temperature (<i>xxx.x</i>)	098.6 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	077 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	080 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742253

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

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

US3742253

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:12:49

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

25 SEP 2020

US3742253

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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 _____

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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)	

US3742253

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

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.

US3742253

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:12:49

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD28

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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)	
Height (<i>xxx.x</i>)	
Weight (<i>xxx.x</i>)	
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)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 OCT 2020

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

US3742253

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:12:49

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 OCT 2020

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD28

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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)	
Height (<i>xxx.x</i>)	
Weight (<i>xxx.x</i>)	
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)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 OCT 2020

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

US3742253

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:12:49

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 OCT 2020

US3742253

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:12:49

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

AEID	USA-US127-2020-MRNA-1273-P30 1000004
Adverse event	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)	20 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	29 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	388 of 1958

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

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

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:12:49

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

Yes ☒

No ☐

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

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

Name of Medication	ASPIRIN
Prophylaxis	Yes ☒ No ☐
Indication	PROPHYLAXIS OF COVID-RELATED HYPERCOAGULABILITY
Dose per administration	81
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 ☐

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

Name of Medication	VITAMIN C
Prophylaxis	Yes ☒ No ☐
Indication	HEALTH MAINTENANCE PROPHYLAXIS
Dose per administration	2
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 ☐

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ☒ No ☐
Indication	INFLUENZA PROPHYLAXIS
Dose per administration	0.5
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 ☒

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

	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)		07 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		07 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3742253

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:12:49

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3742253

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:12:49

Date of dosing discontinuation (dd MMM yyyy)

3 OCT 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

US3742253

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:12:49

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 ☐

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

SAEID	USA-US127-2020-MRNA-1273-P301000004
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:12:49

SAEID	USA-US127-2020-MRNA-1273-P301000004
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	14/OCT/2020 09:17
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

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:12:49

SAEID	USA-US127-2020-MRNA-1273-P301000004
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	23/OCT/2020 00:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:12:49

SAEID	USA-US127-2020-MRNA-1273-P301000004
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	28/OCT/2020 19:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3742253 (Prod: University of Maryland School of Medicine)

US3742253

Form: Participant Creation

Generated On: 26 Nov 2020 11:12:49

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:08
User entered 'US3742253'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:14:24

US3742253

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:35:06
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:10:39

US3742253

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:35:06
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:14:25

US3742253

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:35:06
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:10:39

US3742253

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	04 Sep 2020 15:10:39

US3742253

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:30
User entered (b) (6) 1976'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:14:26

US3742253

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:30
User entered '44'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:11:16

US3742253

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	04 Sep 2020 15:11:16

US3742253

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '44'	System	04 Sep 2020 15:11:37

US3742253

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:30
User entered 'Male (M)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:11:16

US3742253

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:30
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:11:16

US3742253

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:30
User entered '1'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:11:16

US3742253

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:30
User entered '0'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:11:16

US3742253

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:30
User entered '0'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:11:16

US3742253

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:30
User entered '0'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:11:16

US3742253

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:30
User entered '0'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:11:16

US3742253

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:30
User entered '0'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:11:16

US3742253

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:30
User entered empty.	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:11:16

US3742253

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:30
User entered '0'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:11:16

US3742253

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:49

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:30
User entered '0'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:11:16

US3742253

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:33:59
User closed query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 20:07:37
Query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' answered with 'date updated with 0' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 20:47:12
User entered '04 Sep 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 20:47:07
User opened query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 19:55:40
User entered '4 Sep 2020'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:11:37

US3742253

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	04 Sep 2020 15:11:37

US3742253

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '2020'	System	04 Sep 2020 15:11:37

US3742253

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:33:59
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 15:12:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 15:12:03
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Hassan Haji (b) (4)	04 Sep 2020 15:12:03
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 15:11:37
User entered empty.	Hassan Haji (b) (4)	04 Sep 2020 15:11:37

US3742253

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:33:59
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:11:37

US3742253

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:33:59
User entered empty.	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:11:37

US3742253

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:33:59
User entered empty.	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:11:37

US3742253

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:33:59
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:11:37

US3742253

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:33:59
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:14:25

US3742253

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:49

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 15:12:34

US3742253

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:05
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:12:34

US3742253

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:12:49

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:10
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:19:51

US3742253

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:20
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Pigmentation disorders, HLT: Hypopigmentation disorders, PT: Vitiligo, LLT: Vitiligo - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 19:21:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	04 Sep 2020 19:21:42
User entered 'vitiligo'	System	04 Sep 2020 19:21:04
	Hassan Haji (b) (4)	04 Sep 2020 19:21:01
	(b) (4)	

US3742253

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:20
User entered 'UN UNK 1985' reason for change:	(b) (4)	
Data Entry Error	Hassan Haji (b) (4)	04 Sep 2020 19:22:28
User entered '4 Sep 2020'	(b) (4)	
	Hassan Haji (b) (4)	04 Sep 2020 19:21:01
	(b) (4)	

US3742253

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:20
User entered '0'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:21:01

US3742253

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:20
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:21:01

US3742253

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:20
User entered empty.	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:21:01

US3742253

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:20
User entered '0'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:21:01

US3742253

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	04 Sep 2020 19:22:28
User entered 'Sep 2020'	System	04 Sep 2020 19:21:01

US3742253

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '1985'	System	04 Sep 2020 19:22:28
User entered '2020'	System	04 Sep 2020 19:21:01

US3742253

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 19:21:01

US3742253

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 19:21:01

US3742253

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:20
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:22:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:22:44
Data point term sent to Coder	System	04 Sep 2020 19:22:07
User entered 'allergy to penicillin'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:21:43

US3742253

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:20
User entered 'UN UNK 1976' reason for change:	(b) (4)	
Data Entry Error	Hassan Haji (b) (4)	04 Sep 2020 19:22:00
User entered '4 Sep 2020'	(b) (4)	
	Hassan Haji (b) (4)	04 Sep 2020 19:21:43
	(b) (4)	

US3742253

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:20
User entered '0'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:21:43

US3742253

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:20
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:21:43

US3742253

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:20
User entered empty.	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:21:43

US3742253

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:20
User entered '0'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:21:43

US3742253

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered (b) (6) 1976'	System	04 Sep 2020 19:22:00
User entered 'Sep 2020'	System	04 Sep 2020 19:21:43

US3742253

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '1976'	System	04 Sep 2020 19:22:00
User entered '2020'	System	04 Sep 2020 19:21:43

US3742253

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 19:21:43

US3742253

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 19:21:43

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:25
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:24:49

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:25
User closed query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 14:58:56
Query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' answered with 'date updated with 0' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 20:46:20
User entered '04 Sep 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 20:46:16
User opened query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 19:55:46
User entered '4 Sep 2020'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:24:49

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:25
User entered '10:05'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:24:49

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '04 Sep 2020 10:05'	System	14 Sep 2020 20:46:16
User entered '4 Sep 2020 10:05'	System	04 Sep 2020 19:24:49

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:25
User entered '67.0' in	Hassan Haji (b) (4)	04 Sep 2020 19:24:49
DataPoint set to visible.	(b) (4) System	04 Sep 2020 15:12:34

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:25
User entered '167.5' lb	Hassan Haji (b) (4)	04 Sep 2020 19:24:49
DataPoint set to visible.	(b) (4) System	04 Sep 2020 15:12:34

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '26.28906'	System	04 Sep 2020 19:24:49
DataPoint set to visible.	System	04 Sep 2020 15:12:34

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	04 Sep 2020 19:24:49
DataPoint set to visible.	System	04 Sep 2020 15:12:34

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:25
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP since the subject is screened, enrolled, randomized, and dose on the same day. Please update accordingly	(b) (4), (b) (6)	23 Sep 2020 14:49:17
' (Site from DM). Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP since the subject is screened, enrolled, randomized, and dose on the same day. Please update accordingly	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 20:36:01
' answered with 'ENTERED IN ERROR' (Site from DM). User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 20:35:56
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP since the subject is screened, enrolled, randomized, and dose on the same day. Please update accordingly	(b) (4), (b) (6)	17 Sep 2020 07:56:37
' (Site from DM). User entered '098.2' F	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:24:49

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:25
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 20:35:56
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	04 Sep 2020 19:24:49

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:25
User entered empty.	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:24:49

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 20:35:56
User entered '055'	Hassan Haji (b) (4)	04 Sep 2020 19:24:49

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Sep 2020 19:24:49

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 20:35:56
User entered '12'	Hassan Haji (b) (4)	04 Sep 2020 19:24:49

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Sep 2020 19:24:49

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 20:35:56
User entered '130'	(b) (4)	
	Hassan Haji (b) (4)	04 Sep 2020 19:24:49
	(b) (4)	

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 19:24:49

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 20:35:56
User entered '088'	Hassan Haji (b) (4)	04 Sep 2020 19:24:49

US3742253

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 19:24:49

US3742253

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Nov 2020 18:05:35
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	02 Nov 2020 18:05:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	04 Sep 2020 19:24:57
	(b) (4)	

US3742253

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Nov 2020 18:05:35
	(b) (4)	
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	02 Nov 2020 18:05:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:34
	(b) (4), (b) (6)	
User closed query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 20:19:10
	(b) (4), (b) (6)	
Query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' answered with 'date updated with 0' (Site from DM).	Kaitlin Mason (b) (4)	14 Sep 2020 20:45:52
	(b) (4)	
User entered '04 Sep 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	14 Sep 2020 20:45:48
	(b) (4)	
User opened query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 19:55:51
	(b) (4), (b) (6)	
User entered '4 Sep 2020'	Hassan Haji (b) (4)	04 Sep 2020 19:24:57
	(b) (4)	

US3742253

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

US3742253

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

US3742253

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

US3742253

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

US3742253

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

US3742253

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

US3742253

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

US3742253

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

US3742253

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

US3742253

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

Other

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

US3742253

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

US3742253

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

US3742253

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

US3742253

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

US3742253

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

Other

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

US3742253

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:49

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:34:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:34

US3742253

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:01
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:50

US3742253

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:01
User closed query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 20:23:43
Query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' answered with 'date updated with 0' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 20:46:47
User entered '04 Sep 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 20:46:44
User opened query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 19:55:55
User entered '4 Sep 2020'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:50

US3742253

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:01
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:25:50

US3742253

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	04 Sep 2020 19:25:50

US3742253

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:05
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:54:30

US3742253

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:05
User entered '111756'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:54:30

US3742253

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:05
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:54:30

US3742253

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:05
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:26:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:05
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:26:25

US3742253

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:05
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:26:25

US3742253

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:05
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:26:25

US3742253

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:05
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:26:25

US3742253

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:05
User entered 'No (N)'	Kaitlin Mason (b) (4)	21 Sep 2020 20:36:11
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 05:22:04
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:22:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:49

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 07:19:13
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' answered with 'ENTERED IN ERROR' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 20:36:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 20:36:27
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 12:33:57
User entered '67.0' in	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:49

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 20:36:27
User entered '167.5' lb	(b) (4)	
	Hassan Haji (b) (4)	04 Sep 2020 19:28:31
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:49

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 07:19:13
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' answered with 'ENTERED IN ERROR' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 20:36:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 20:36:27
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 12:33:57
User entered '67.0' in	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:49

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 20:36:27
User entered '167.5' lb	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered '4 Sep 2020'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered '10:05'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '4 Sep 2020 10:05'	System	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered '098.2' F	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered 'Oral (Oral)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered empty.	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered '055'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered '12'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered '130'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered '088'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:49

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 07:19:13
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' answered with 'ENTERED IN ERROR' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 20:36:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 20:36:27
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 12:33:57
User entered '67.0' in	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:49

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 20:36:27
User entered '167.5' lb	(b) (4)	
	Hassan Haji (b) (4)	04 Sep 2020 19:28:31
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered '4 Sep 2020'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered '11:38'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '4 Sep 2020 11:38'	System	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered '97.4' F	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered 'Other (Other)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered 'temporal'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered '055'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered '14'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered '134'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:32
User entered '089'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 19:28:31

US3742253

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Was the physical examination performed?

Audit	User	Time (GMT)
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Nov 2020 18:05:50
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	02 Nov 2020 18:05:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:42
	(b) (4), (b) (6)	
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 16:52:45
	(b) (4), (b) (6)	
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' answered with 'DATA REMOVED TO PREVENT DATA DUPLICATION' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 20:29:02
	(b) (4), (b) (6)	
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 20:28:48
	(b) (4), (b) (6)	
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 18:26:29
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	04 Sep 2020 19:29:59
	(b) (4)	

US3742253

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Nov 2020 18:05:50
	(b) (4)	
User entered '04 Sep 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	02 Nov 2020 18:05:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:42
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 20:28:48
	(b) (4)	
User entered '4 Sep 2020'	Hassan Haji (b) (4)	04 Sep 2020 19:29:59
	(b) (4)	

US3742253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:48
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	04 Sep 2020 15:35:06
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	04 Sep 2020 15:35:06
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	04 Sep 2020 15:15:23
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	04 Sep 2020 15:15:23

US3742253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:48
User entered empty.	Kaitlin Mason (b) (4)	04 Sep 2020 15:15:23
	(b) (4)	

US3742253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:48
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	04 Sep 2020 15:15:23

US3742253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 15:15:23

US3742253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:48
User entered '4 Sep 2020'	Kaitlin Mason (b) (4)	04 Sep 2020 15:15:23
	(b) (4)	

US3742253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:48
User entered '11:06' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	04 Sep 2020 15:35:06
User entered empty.	(b) (4)	
	Kaitlin Mason (b) (4)	04 Sep 2020 15:15:23
	(b) (4)	

US3742253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '4 Sep 2020 11:06'	System	04 Sep 2020 15:35:06
User entered empty.	System	04 Sep 2020 15:15:23

US3742253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:48
User entered 'Left Arm (LEFT ARM)'	Kaitlin Mason (b) (4) (b) (4)	04 Sep 2020 15:15:23

US3742253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:48
User entered 'ONCE'	System	04 Sep 2020 15:15:23

US3742253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 15:15:23

US3742253

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:54
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:13:10

US3742253

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:54
User entered '4 Sep 2020'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:13:10

US3742253

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:36:54
User entered '10:26'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:13:10

US3742253

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '4 Sep 2020 10:26'	System	04 Sep 2020 15:13:10

US3742253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:35:34
User entered '4 Sep 2020'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:13:30

US3742253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:49

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:13:30

US3742253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:35:34
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:13:30

US3742253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:35:34
User entered '10:29'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:13:30

US3742253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '4 Sep 2020 10:29'	System	04 Sep 2020 15:13:30

US3742253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:49

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:13:30

US3742253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:35:34
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:13:30

US3742253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:35:34
User entered empty.	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 15:13:30

US3742253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 15:13:30

US3742253

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:35:39
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:30:15

US3742253

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 19:30:15

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T11:37:34', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '3df27672-eec2-4b26-aeb2-8ca984c68a71'	System	04 Sep 2020 15:38:08
User entered 'Yes (Y)'	System	04 Sep 2020 15:38:08

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T11:37:53', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '3df27672-eec2-4b26-aeb2-8ca984c68a71'	System	04 Sep 2020 15:38:08
User entered '97.4'	System	04 Sep 2020 15:38:08

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T11:37:56', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '3df27672-eec2-4b26-aeb2-8ca984c68a71'	System	04 Sep 2020 15:38:08
User entered 'No (N)'	System	04 Sep 2020 15:38:08

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T11:38:04', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '3df27672-eec2-4b26-aeb2-8ca984c68a71'	System	04 Sep 2020 15:38:08
User entered '04 Sep 2020 11:38'	System	04 Sep 2020 15:38:08

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:26'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 13:56'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T22:40:32', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '67b17261-1438-4b73-8de1-0c8a98cf4e3a'	System	05 Sep 2020 02:40:48
User entered 'Yes (Y)'	System	05 Sep 2020 02:40:48

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T22:40:39', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '67b17261-1438-4b73-8de1-0c8a98cf4e3a' User entered '97.8'	System	05 Sep 2020 02:40:48
	System	05 Sep 2020 02:40:48

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T22:40:42', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '67b17261-1438-4b73-8de1-0c8a98cf4e3a'	System	05 Sep 2020 02:40:48
User entered 'No (N)'	System	05 Sep 2020 02:40:48

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T22:40:46', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '67b17261-1438-4b73-8de1-0c8a98cf4e3a'	System	05 Sep 2020 02:40:48
User entered '04 Sep 2020 22:40'	System	05 Sep 2020 02:40:48

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 14:51'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 2'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-05T21:02:20', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'e3707a29-48c5-4392-9709-35c2fe9ae1db'	System	06 Sep 2020 01:02:46
User entered 'Yes (Y)'	System	06 Sep 2020 01:02:46

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-05T21:02:35', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'e3707a29-48c5-4392-9709-35c2fe9ae1db'	System	06 Sep 2020 01:02:46
User entered '98.7'	System	06 Sep 2020 01:02:46

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-05T21:02:38', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'e3707a29-48c5-4392-9709-35c2fe9ae1db'	System	06 Sep 2020 01:02:46
User entered 'No (N)'	System	06 Sep 2020 01:02:46

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-05T21:02:44', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'e3707a29-48c5-4392-9709-35c2fe9ae1db'	System	06 Sep 2020 01:02:46
User entered '05 Sep 2020 21:02'	System	06 Sep 2020 01:02:46

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 3'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-06T12:26:37', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'bbab9a00-efa9-4070-842a-7b2765b7eb8b'	System	06 Sep 2020 16:26:50
User entered 'Yes (Y)'	System	06 Sep 2020 16:26:50

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-06T12:26:40', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'bbab9a00-efa9-4070-842a-7b2765b7eb8b' User entered '97.8'	System	06 Sep 2020 16:26:50
	System	06 Sep 2020 16:26:50

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-06T12:26:44', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'bbab9a00-efa9-4070-842a-7b2765b7eb8b'	System	06 Sep 2020 16:26:50
User entered 'No (N)'	System	06 Sep 2020 16:26:50

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-06T12:26:47', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'bbab9a00-efa9-4070-842a-7b2765b7eb8b'	System	06 Sep 2020 16:26:50
User entered '06 Sep 2020 12:26'	System	06 Sep 2020 16:26:50

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 4'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T05:53:26', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'e4b4e345-8283-4498-aa16-cff331d3a683'	System	08 Sep 2020 09:53:41
User entered 'Yes (Y)'	System	08 Sep 2020 09:53:41

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T05:53:32', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'e4b4e345-8283-4498-aa16-cff331d3a683'	System	08 Sep 2020 09:53:41
User entered '98.8'	System	08 Sep 2020 09:53:41

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T05:53:35', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'e4b4e345-8283-4498-aa16-cff331d3a683'	System	08 Sep 2020 09:53:41
User entered 'No (N)'	System	08 Sep 2020 09:53:41

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T05:53:39', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'e4b4e345-8283-4498-aa16-cff331d3a683' User entered '08 Sep 2020 05:53'	System	08 Sep 2020 09:53:41
	System	08 Sep 2020 09:53:41

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 5'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T12:01:14', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '831e5569-5a79-4b82-9c49-d35205694999'	System	08 Sep 2020 16:02:15
User entered 'Yes (Y)'	System	08 Sep 2020 16:02:15

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T12:01:17', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '831e5569-5a79-4b82-9c49-d35205694999'	System	08 Sep 2020 16:02:15
User entered '97.8'	System	08 Sep 2020 16:02:15

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T12:01:19', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '831e5569-5a79-4b82-9c49-d35205694999'	System	08 Sep 2020 16:02:15
User entered 'No (N)'	System	08 Sep 2020 16:02:15

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T12:01:21', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '831e5569-5a79-4b82-9c49-d35205694999'	System	08 Sep 2020 16:02:15
User entered '08 Sep 2020 12:01'	System	08 Sep 2020 16:02:15

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 6'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-09T21:52:02', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'ab2c6175-f839-498a-ac7d-b2683f5da96f'	System	10 Sep 2020 01:52:14
User entered 'Yes (Y)'	System	10 Sep 2020 01:52:14

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-09T21:52:06', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'ab2c6175-f839-498a-ac7d-b2683f5da96f'	System	10 Sep 2020 01:52:14
User entered '98.2'	System	10 Sep 2020 01:52:14

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-09T21:52:08', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'ab2c6175-f839-498a-ac7d-b2683f5da96f'	System	10 Sep 2020 01:52:14
User entered 'No (N)'	System	10 Sep 2020 01:52:14

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-09T21:52:10', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'ab2c6175-f839-498a-ac7d-b2683f5da96f'	System	10 Sep 2020 01:52:14
User entered '09 Sep 2020 21:52'	System	10 Sep 2020 01:52:14

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 7'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-11T06:04:19', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '658fa9d0-6cdc-447d-af75-1791b64f6c84'	System	11 Sep 2020 10:04:46
User entered 'Yes (Y)'	System	11 Sep 2020 10:04:46

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-11T06:04:23', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '658fa9d0-6cdc-447d-af75-1791b64f6c84'	System	11 Sep 2020 10:04:46
User entered '98.0'	System	11 Sep 2020 10:04:46

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-11T06:04:26', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '658fa9d0-6cdc-447d-af75-1791b64f6c84'	System	11 Sep 2020 10:04:46
User entered 'No (N)'	System	11 Sep 2020 10:04:46

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-11T06:04:32', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '658fa9d0-6cdc-447d-af75-1791b64f6c84'	System	11 Sep 2020 10:04:46
User entered '11 Sep 2020 06:04'	System	11 Sep 2020 10:04:46

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T11:37:04', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'd805541c-31cb-4195-978a-156d396591a0'	System	04 Sep 2020 15:37:25
User entered 'None (1)'	System	04 Sep 2020 15:37:25

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T11:37:06', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'd805541c-31cb-4195-978a-156d396591a0'	System	04 Sep 2020 15:37:25
User entered 'No (N)'	System	04 Sep 2020 15:37:25

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T11:37:08', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'd805541c-31cb-4195-978a-156d396591a0'	System	04 Sep 2020 15:37:25
User entered 'No (N)'	System	04 Sep 2020 15:37:25

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T11:37:20', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'd805541c-31cb-4195-978a-156d396591a0'	System	04 Sep 2020 15:37:25
User entered 'None (1)'	System	04 Sep 2020 15:37:25

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T11:37:23', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'd805541c-31cb-4195-978a-156d396591a0'	System	04 Sep 2020 15:37:25
User entered '04 Sep 2020 11:37'	System	04 Sep 2020 15:37:25

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:26'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 13:56'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T22:40:50', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '1291d8ad-75cf-45dc-b2d2-0e4f1f49cdcb'	System	05 Sep 2020 02:41:05
User entered 'None (1)'	System	05 Sep 2020 02:41:05

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T22:40:53', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '1291d8ad-75cf-45dc-b2d2-0e4f1f49cdcb'	System	05 Sep 2020 02:41:05
User entered 'No (N)'	System	05 Sep 2020 02:41:05

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T22:40:56', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '1291d8ad-75cf-45dc-b2d2-0e4f1f49cdcb'	System	05 Sep 2020 02:41:05
User entered 'No (N)'	System	05 Sep 2020 02:41:05

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T22:40:59', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '1291d8ad-75cf-45dc-b2d2-0e4f1f49cdcb'	System	05 Sep 2020 02:41:05
User entered 'None (1)'	System	05 Sep 2020 02:41:05

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T22:41:02', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '1291d8ad-75cf-45dc-b2d2-0e4f1f49cdcb'	System	05 Sep 2020 02:41:05
User entered '04 Sep 2020 22:41'	System	05 Sep 2020 02:41:05

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 14:51'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 2'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

[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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-05T21:02:49', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '8ddb20e3-768f-4bce-8400-967512b5dbed'	System	06 Sep 2020 01:03:02
User entered 'None (1)'	System	06 Sep 2020 01:03:02

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-05T21:02:51', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '8ddb20e3-768f-4bce-8400-967512b5dbed'	System	06 Sep 2020 01:03:02
User entered 'No (N)'	System	06 Sep 2020 01:03:02

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-05T21:02:53', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '8ddb20e3-768f-4bce-8400-967512b5dbed'	System	06 Sep 2020 01:03:02
User entered 'No (N)'	System	06 Sep 2020 01:03:02

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

[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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-05T21:02:56', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '8ddb20e3-768f-4bce-8400-967512b5dbed'	System	06 Sep 2020 01:03:02
User entered 'None (1)'	System	06 Sep 2020 01:03:02

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-05T21:02:58', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '8ddb20e3-768f-4bce-8400-967512b5dbed' User entered '05 Sep 2020 21:02'	System	06 Sep 2020 01:03:02
	System	06 Sep 2020 01:03:02

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 3'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

[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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-06T12:26:50', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '5abb177c-2798-47a0-a30e-e6a0e678c938'	System	06 Sep 2020 16:27:00
User entered 'None (1)'	System	06 Sep 2020 16:27:00

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-06T12:26:53', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '5abb177c-2798-47a0-a30e-e6a0e678c938'	System	06 Sep 2020 16:27:00
User entered 'No (N)'	System	06 Sep 2020 16:27:00

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-06T12:26:54', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '5abb177c-2798-47a0-a30e-e6a0e678c938'	System	06 Sep 2020 16:27:00
User entered 'No (N)'	System	06 Sep 2020 16:27:00

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

[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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-06T12:26:56', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '5abb177c-2798-47a0-a30e-e6a0e678c938'	System	06 Sep 2020 16:27:00
User entered 'None (1)'	System	06 Sep 2020 16:27:00

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-06T12:26:58', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '5abb177c-2798-47a0-a30e-e6a0e678c938'	System	06 Sep 2020 16:27:00
User entered '06 Sep 2020 12:26'	System	06 Sep 2020 16:27:00

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 4'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

[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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T05:53:43', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'b1570f9e-0abd-4e14-afb1-6c1b87b7d6fa'	System	08 Sep 2020 09:54:01
User entered 'None (1)'	System	08 Sep 2020 09:54:01

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T05:53:45', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'b1570f9e-0abd-4e14-afb1-6c1b87b7d6fa'	System	08 Sep 2020 09:54:01
User entered 'No (N)'	System	08 Sep 2020 09:54:01

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T05:53:48', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'b1570f9e-0abd-4e14-afb1-6c1b87b7d6fa'	System	08 Sep 2020 09:54:01
User entered 'No (N)'	System	08 Sep 2020 09:54:01

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

[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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T05:53:50', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'b1570f9e-0abd-4e14-afb1-6c1b87b7d6fa'	System	08 Sep 2020 09:54:01
User entered 'None (1)'	System	08 Sep 2020 09:54:01

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T05:53:55', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'b1570f9e-0abd-4e14-afb1-6c1b87b7d6fa' User entered '08 Sep 2020 05:53'	System	08 Sep 2020 09:54:01
	System	08 Sep 2020 09:54:01

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 5'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

[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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T12:01:31', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '99e2a910-c314-4d04-aae0-c9880fe8c295'	System	08 Sep 2020 16:03:35
User entered 'None (1)'	System	08 Sep 2020 16:03:35

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T12:02:15', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '99e2a910-c314-4d04-aae0-c9880fe8c295'	System	08 Sep 2020 16:03:35
User entered 'No (N)'	System	08 Sep 2020 16:03:35

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T12:02:20', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '99e2a910-c314-4d04-aae0-c9880fe8c295'	System	08 Sep 2020 16:03:35
User entered 'No (N)'	System	08 Sep 2020 16:03:35

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T12:02:30', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '99e2a910-c314-4d04-aae0-c9880fe8c295'	System	08 Sep 2020 16:03:35
User entered 'None (1)'	System	08 Sep 2020 16:03:35

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T12:02:43', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '99e2a910-c314-4d04-aae0-c9880fe8c295'	System	08 Sep 2020 16:03:35
User entered '08 Sep 2020 12:02'	System	08 Sep 2020 16:03:35

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 6'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

[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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-09T21:52:14', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '586d25a6-772c-43a4-90fd-5a827aa211ff'	System	10 Sep 2020 01:52:29
User entered 'None (1)'	System	10 Sep 2020 01:52:29

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-09T21:52:16', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '586d25a6-772c-43a4-90fd-5a827aa211ff'	System	10 Sep 2020 01:52:29
User entered 'No (N)'	System	10 Sep 2020 01:52:29

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-09T21:52:18', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '586d25a6-772c-43a4-90fd-5a827aa211ff'	System	10 Sep 2020 01:52:29
User entered 'No (N)'	System	10 Sep 2020 01:52:29

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

[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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-09T21:52:22', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '586d25a6-772c-43a4-90fd-5a827aa211ff'	System	10 Sep 2020 01:52:29
User entered 'None (1)'	System	10 Sep 2020 01:52:29

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-09T21:52:25', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '586d25a6-772c-43a4-90fd-5a827aa211ff'	System	10 Sep 2020 01:52:29
User entered '09 Sep 2020 21:52'	System	10 Sep 2020 01:52:29

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 7'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

[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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-11T06:04:37', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '6fb973af-2949-40bb-856c-be779d66d20c'	System	11 Sep 2020 10:05:03
User entered 'None (1)'	System	11 Sep 2020 10:05:03

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-11T06:04:39', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '6fb973af-2949-40bb-856c-be779d66d20c'	System	11 Sep 2020 10:05:03
User entered 'No (N)'	System	11 Sep 2020 10:05:03

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-11T06:04:42', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '6fb973af-2949-40bb-856c-be779d66d20c'	System	11 Sep 2020 10:05:03
User entered 'No (N)'	System	11 Sep 2020 10:05:03

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

[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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-11T06:04:44', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '6fb973af-2949-40bb-856c-be779d66d20c'	System	11 Sep 2020 10:05:03
User entered 'None (1)'	System	11 Sep 2020 10:05:03

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-11T06:04:48', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '6fb973af-2949-40bb-856c-be779d66d20c'	System	11 Sep 2020 10:05:03
User entered '11 Sep 2020 06:04'	System	11 Sep 2020 10:05:03

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T11:36:34', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'e7341c78-07da-4271-b7c4-78021b6e0ee3'	System	04 Sep 2020 15:37:01
User entered 'None (0)'	System	04 Sep 2020 15:37:01

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T11:36:37', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'e7341c78-07da-4271-b7c4-78021b6e0ee3'	System	04 Sep 2020 15:37:01
User entered 'None (0)'	System	04 Sep 2020 15:37:01

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T11:36:39', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'e7341c78-07da-4271-b7c4-78021b6e0ee3'	System	04 Sep 2020 15:37:01
User entered 'None (0)'	System	04 Sep 2020 15:37:01

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T11:36:41', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'e7341c78-07da-4271-b7c4-78021b6e0ee3'	System	04 Sep 2020 15:37:01
User entered 'None (0)'	System	04 Sep 2020 15:37:01

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T11:36:43', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'e7341c78-07da-4271-b7c4-78021b6e0ee3'	System	04 Sep 2020 15:37:01
User entered 'None (0)'	System	04 Sep 2020 15:37:01

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T11:36:45', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'e7341c78-07da-4271-b7c4-78021b6e0ee3' User entered 'None (0)'	System	04 Sep 2020 15:37:01
	System	04 Sep 2020 15:37:01

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T11:36:53', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'e7341c78-07da-4271-b7c4-78021b6e0ee3'	System	04 Sep 2020 15:37:01
User entered 'No (N)'	System	04 Sep 2020 15:37:01

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T11:36:57', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'e7341c78-07da-4271-b7c4-78021b6e0ee3'	System	04 Sep 2020 15:37:01
User entered '04 Sep 2020 11:36'	System	04 Sep 2020 15:37:01

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:26'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 13:56'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T22:41:07', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '30843951-19cd-4d4f-b72d-009b8c0ba150'	System	05 Sep 2020 02:41:25
User entered 'None (0)'	System	05 Sep 2020 02:41:25

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T22:41:09', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '30843951-19cd-4d4f-b72d-009b8c0ba150'	System	05 Sep 2020 02:41:25
User entered 'None (0)'	System	05 Sep 2020 02:41:25

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T22:41:11', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '30843951-19cd-4d4f-b72d-009b8c0ba150'	System	05 Sep 2020 02:41:25
User entered 'None (0)'	System	05 Sep 2020 02:41:25

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T22:41:13', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '30843951-19cd-4d4f-b72d-009b8c0ba150'	System	05 Sep 2020 02:41:25
User entered 'None (0)'	System	05 Sep 2020 02:41:25

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T22:41:15', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '30843951-19cd-4d4f-b72d-009b8c0ba150'	System	05 Sep 2020 02:41:25
User entered 'None (0)'	System	05 Sep 2020 02:41:25

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T22:41:17', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '30843951-19cd-4d4f-b72d-009b8c0ba150'	System	05 Sep 2020 02:41:25
User entered 'None (0)'	System	05 Sep 2020 02:41:25

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T22:41:20', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '30843951-19cd-4d4f-b72d-009b8c0ba150'	System	05 Sep 2020 02:41:25
User entered 'No (N)'	System	05 Sep 2020 02:41:25

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-04T22:41:23', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '30843951-19cd-4d4f-b72d-009b8c0ba150'	System	05 Sep 2020 02:41:25
User entered '04 Sep 2020 22:41'	System	05 Sep 2020 02:41:25

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 14:51'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 2'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-05T21:03:01', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '0743480f-4213-475b-97bf-73759a4cc3c8'	System	06 Sep 2020 01:03:22
User entered 'None (0)'	System	06 Sep 2020 01:03:22

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-05T21:03:05', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '0743480f-4213-475b-97bf-73759a4cc3c8'	System	06 Sep 2020 01:03:22
User entered 'None (0)'	System	06 Sep 2020 01:03:22

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-05T21:03:07', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '0743480f-4213-475b-97bf-73759a4cc3c8'	System	06 Sep 2020 01:03:22
User entered 'None (0)'	System	06 Sep 2020 01:03:22

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-05T21:03:10', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '0743480f-4213-475b-97bf-73759a4cc3c8'	System	06 Sep 2020 01:03:22
User entered 'None (0)'	System	06 Sep 2020 01:03:22

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-05T21:03:12', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '0743480f-4213-475b-97bf-73759a4cc3c8'	System	06 Sep 2020 01:03:22
User entered 'None (0)'	System	06 Sep 2020 01:03:22

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-05T21:03:13', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '0743480f-4213-475b-97bf-73759a4cc3c8'	System	06 Sep 2020 01:03:22
User entered 'None (0)'	System	06 Sep 2020 01:03:22

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-05T21:03:16', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '0743480f-4213-475b-97bf-73759a4cc3c8'	System	06 Sep 2020 01:03:22
User entered 'No (N)'	System	06 Sep 2020 01:03:22

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-05T21:03:18', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '0743480f-4213-475b-97bf-73759a4cc3c8'	System	06 Sep 2020 01:03:22
User entered '05 Sep 2020 21:03'	System	06 Sep 2020 01:03:22

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 3'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-06T12:27:01', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '4eb6b648-839a-4d5b-937b-5570cf23de9a'	System	06 Sep 2020 16:27:14
User entered 'None (0)'	System	06 Sep 2020 16:27:14

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-06T12:27:02', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '4eb6b648-839a-4d5b-937b-5570cf23de9a'	System	06 Sep 2020 16:27:14
User entered 'None (0)'	System	06 Sep 2020 16:27:14

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-06T12:27:04', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '4eb6b648-839a-4d5b-937b-5570cf23de9a'	System	06 Sep 2020 16:27:14
User entered 'None (0)'	System	06 Sep 2020 16:27:14

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-06T12:27:05', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '4eb6b648-839a-4d5b-937b-5570cf23de9a'	System	06 Sep 2020 16:27:14
User entered 'None (0)'	System	06 Sep 2020 16:27:14

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-06T12:27:07', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '4eb6b648-839a-4d5b-937b-5570cf23de9a'	System	06 Sep 2020 16:27:14
User entered 'None (0)'	System	06 Sep 2020 16:27:14

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-06T12:27:09', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '4eb6b648-839a-4d5b-937b-5570cf23de9a'	System	06 Sep 2020 16:27:14
User entered 'None (0)'	System	06 Sep 2020 16:27:14

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-06T12:27:10', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '4eb6b648-839a-4d5b-937b-5570cf23de9a'	System	06 Sep 2020 16:27:14
User entered 'No (N)'	System	06 Sep 2020 16:27:14

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-06T12:27:12', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '4eb6b648-839a-4d5b-937b-5570cf23de9a'	System	06 Sep 2020 16:27:14
User entered '06 Sep 2020 12:27'	System	06 Sep 2020 16:27:14

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 4'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T05:54:01', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'ec3c4d97-f87e-4595-8392-ecc015165e68'	System	08 Sep 2020 09:54:22
User entered 'None (0)'	System	08 Sep 2020 09:54:22

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T05:54:04', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'ec3c4d97-f87e-4595-8392-ecc015165e68'	System	08 Sep 2020 09:54:22
User entered 'None (0)'	System	08 Sep 2020 09:54:22

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T05:54:05', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'ec3c4d97-f87e-4595-8392-ecc015165e68'	System	08 Sep 2020 09:54:22
User entered 'None (0)'	System	08 Sep 2020 09:54:22

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T05:54:07', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'ec3c4d97-f87e-4595-8392-ecc015165e68'	System	08 Sep 2020 09:54:22
User entered 'None (0)'	System	08 Sep 2020 09:54:22

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T05:54:08', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'ec3c4d97-f87e-4595-8392-ecc015165e68'	System	08 Sep 2020 09:54:22
User entered 'None (0)'	System	08 Sep 2020 09:54:22

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T05:54:10', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'ec3c4d97-f87e-4595-8392-ecc015165e68'	System	08 Sep 2020 09:54:22
User entered 'None (0)'	System	08 Sep 2020 09:54:22

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T05:54:12', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'ec3c4d97-f87e-4595-8392-ecc015165e68'	System	08 Sep 2020 09:54:22
User entered 'No (N)'	System	08 Sep 2020 09:54:22

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T05:54:14', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'ec3c4d97-f87e-4595-8392-ecc015165e68'	System	08 Sep 2020 09:54:22
User entered '08 Sep 2020 05:54'	System	08 Sep 2020 09:54:22

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 5'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T12:02:47', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '9bfc7548-4819-4270-b1fe-ea32bcea98b7'	System	09 Sep 2020 02:39:05
User entered 'None (0)'	System	09 Sep 2020 02:39:05

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T12:02:48', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '9bfc7548-4819-4270-b1fe-ea32bcea98b7'	System	09 Sep 2020 02:39:05
User entered 'None (0)'	System	09 Sep 2020 02:39:05

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T12:02:49', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '9bfc7548-4819-4270-b1fe-ea32bcea98b7'	System	09 Sep 2020 02:39:05
User entered 'None (0)'	System	09 Sep 2020 02:39:05

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T12:02:51', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '9bfc7548-4819-4270-b1fe-ea32bcea98b7'	System	09 Sep 2020 02:39:05
User entered 'None (0)'	System	09 Sep 2020 02:39:05

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T12:02:52', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '9bfc7548-4819-4270-b1fe-ea32bcea98b7'	System	09 Sep 2020 02:39:05
User entered 'None (0)'	System	09 Sep 2020 02:39:05

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T12:02:53', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '9bfc7548-4819-4270-b1fe-ea32bcea98b7'	System	09 Sep 2020 02:39:05
User entered 'None (0)'	System	09 Sep 2020 02:39:05

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T12:02:55', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '9bfc7548-4819-4270-b1fe-ea32bcea98b7'	System	09 Sep 2020 02:39:05
User entered 'No (N)'	System	09 Sep 2020 02:39:05

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-08T12:02:57', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '9bfc7548-4819-4270-b1fe-ea32bcea98b7'	System	09 Sep 2020 02:39:05
User entered '08 Sep 2020 12:02'	System	09 Sep 2020 02:39:05

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 6'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-09T21:52:29', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '3541a178-efa8-4667-b56d-ad463ff5c457'	System	10 Sep 2020 01:52:54
User entered 'None (0)'	System	10 Sep 2020 01:52:54

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-09T21:52:30', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '3541a178-efa8-4667-b56d-ad463ff5c457'	System	10 Sep 2020 01:52:54
User entered 'None (0)'	System	10 Sep 2020 01:52:54

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-09T21:52:32', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '3541a178-efa8-4667-b56d-ad463ff5c457'	System	10 Sep 2020 01:52:54
User entered 'None (0)'	System	10 Sep 2020 01:52:54

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-09T21:52:39', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '3541a178-efa8-4667-b56d-ad463ff5c457'	System	10 Sep 2020 01:52:54
User entered 'None (0)'	System	10 Sep 2020 01:52:54

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-09T21:52:42', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '3541a178-efa8-4667-b56d-ad463ff5c457'	System	10 Sep 2020 01:52:54
User entered 'None (0)'	System	10 Sep 2020 01:52:54

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-09T21:52:45', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '3541a178-efa8-4667-b56d-ad463ff5c457'	System	10 Sep 2020 01:52:54
User entered 'None (0)'	System	10 Sep 2020 01:52:54

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-09T21:52:47', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '3541a178-efa8-4667-b56d-ad463ff5c457'	System	10 Sep 2020 01:52:54
User entered 'No (N)'	System	10 Sep 2020 01:52:54

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-09T21:52:49', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '3541a178-efa8-4667-b56d-ad463ff5c457'	System	10 Sep 2020 01:52:54
User entered '09 Sep 2020 21:52'	System	10 Sep 2020 01:52:54

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 7'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-11T06:04:52', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '4f95061d-0f4a-4bca-b15f-42f830492d4d'	System	11 Sep 2020 10:05:14
User entered 'None (0)'	System	11 Sep 2020 10:05:14

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-11T06:04:54', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '4f95061d-0f4a-4bca-b15f-42f830492d4d'	System	11 Sep 2020 10:05:14
User entered 'None (0)'	System	11 Sep 2020 10:05:14

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-11T06:04:55', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '4f95061d-0f4a-4bca-b15f-42f830492d4d'	System	11 Sep 2020 10:05:14
User entered 'None (0)'	System	11 Sep 2020 10:05:14

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-11T06:04:57', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '4f95061d-0f4a-4bca-b15f-42f830492d4d'	System	11 Sep 2020 10:05:14
User entered 'None (0)'	System	11 Sep 2020 10:05:14

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-11T06:04:59', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '4f95061d-0f4a-4bca-b15f-42f830492d4d'	System	11 Sep 2020 10:05:14
User entered 'None (0)'	System	11 Sep 2020 10:05:14

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-11T06:05:02', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '4f95061d-0f4a-4bca-b15f-42f830492d4d'	System	11 Sep 2020 10:05:14
User entered 'None (0)'	System	11 Sep 2020 10:05:14

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-11T06:05:04', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '4f95061d-0f4a-4bca-b15f-42f830492d4d'	System	11 Sep 2020 10:05:14
User entered 'No (N)'	System	11 Sep 2020 10:05:14

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-09-11T06:05:06', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '4f95061d-0f4a-4bca-b15f-42f830492d4d'	System	11 Sep 2020 10:05:14
User entered '11 Sep 2020 06:05'	System	11 Sep 2020 10:05:14

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 15:35:06

US3742253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:17
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	11 Sep 2020 12:09:29

US3742253

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:17
User entered '11 Sep 2020'	Faith Pa'ahana-Brown (b) (4)	11 Sep 2020 12:09:29

US3742253

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:17
User entered 'Contact Made (CONTACT MADE)'	Faith Pa'ahana-Brown (b) (4)	11 Sep 2020 12:09:29

US3742253

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:17
User entered empty.	Faith Pa'ahana-Brown (b) (4)	11 Sep 2020 12:09:29

US3742253

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:32:07
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	11 Sep 2020 12:09:34

US3742253

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 12:09:34

US3742253

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:31:34
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	18 Sep 2020 14:12:02

US3742253

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:31:34
User entered '18 Sep 2020'	Faith Pa'ahana-Brown (b) (4)	18 Sep 2020 14:12:02

US3742253

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:31:34
User entered 'Contact Made (CONTACT MADE)'	Faith Pa'ahana-Brown (b) (4)	18 Sep 2020 14:12:02

US3742253

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:31:34
User entered empty.	Faith Pa'ahana-Brown (b) (4)	18 Sep 2020 14:12:02

US3742253

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:31:22
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	18 Sep 2020 14:12:06

US3742253

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 14:12:06

US3742253

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: based on dates within the Saliva Log and Symptom Log, please advise if a Convalescence Visit Day 28 occurred. if so, please make all appropriate updates or clarify' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:16:47
Query 'Per CDM: based on dates within the Saliva Log and Symptom Log, please advise if a Convalescence Visit Day 28 occurred. if so, please make all appropriate updates or clarify' answered with 'convalescent visit was conducted - documentation is in ecrf' (Site from DM).	Kaitlin Mason (b) (4)	09 Nov 2020 16:00:16
User opened query 'Per CDM: based on dates within the Saliva Log and Symptom Log, please advise if a Convalescence Visit Day 28 occurred. if so, please make all appropriate updates or clarify' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 06:14:57
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:31:57
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	07 Oct 2020 12:56:09

US3742253

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:31:57
User entered '25 Sep 2020'	Sherry McCammon (b) (4)	07 Oct 2020 12:56:09
	(b) (4)	

US3742253

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:31:57
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	07 Oct 2020 12:56:09
	(b) (4)	

US3742253

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:31:57
User entered empty.	Sherry McCammon (b) (4)	07 Oct 2020 12:56:09
	(b) (4)	

US3742253

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:31:46
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	07 Oct 2020 12:56:14
	(b) (4)	

US3742253

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 12:56:14

US3742253

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 22:14:37

US3742253

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:37

US3742253

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:37

US3742253

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	29 Oct 2020 22:14:37

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:14:44

US3742253

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 22:14:49

US3742253

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:49

US3742253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 22:14:56

US3742253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

[If No, reason not given](#)

Audit	User	Time (GMT)
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		30 Oct 2020 15:47:15
User entered 'Confirmed COVID-19 (COVID)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	30 Oct 2020 15:47:15
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	
User entered empty.	System	29 Oct 2020 22:14:56
	(b) (4), (b) (6)	29 Oct 2020 22:14:56

US3742253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:56

US3742253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:14:56

US3742253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:56

US3742253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:56

US3742253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:14:56

US3742253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:14:56

US3742253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:14:56

US3742253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:14:56

US3742253

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 22:15:03

US3742253

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:15:03

US3742253

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:15:03

US3742253

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:15:03

US3742253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:15:19

US3742253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:49

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	29 Oct 2020 22:15:19

US3742253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 22:15:19

US3742253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:15:19

US3742253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:15:19

US3742253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:49

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	29 Oct 2020 22:15:19

US3742253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 22:15:19

US3742253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:15:19

US3742253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:15:19

US3742253

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 22:15:24

US3742253

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 22:15:24

US3742253

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 22:16:01

US3742253

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:16:01

US3742253

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:16:01

US3742253

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Participant in Convalescent period.'	(b) (4), (b) (6)	29 Oct 2020 22:16:01

US3742253

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 22:16:06

US3742253

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 22:16:06

US3742253

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 22:16:26

US3742253

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:16:26

US3742253

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:16:26

US3742253

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Participant in Convalescent period.'	(b) (4), (b) (6)	29 Oct 2020 22:16:26

US3742253

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 22:16:31

US3742253

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 22:16:31

US3742253

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30-OCT-2020 is reported under Visit 3 Day 57 in PPD portal; however, immunogenicity sample is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:13:38
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30-OCT-2020 is reported under Visit 3 Day 57 in PPD portal; however, immunogenicity sample is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	19 Nov 2020 16:02:22
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30-OCT-2020 is reported under Visit 3 Day 57 in PPD portal; however, immunogenicity sample is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:31:28
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 22:16:41

US3742253

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:16:41

US3742253

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:16:41

US3742253

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Participant in Convalescent period.'	(b) (4), (b) (6)	29 Oct 2020 22:16:41

US3742253

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 22:17:01
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 22:16:49

US3742253

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 22:17:01
User entered empty.	System	29 Oct 2020 22:16:49

US3742253

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 16:02:33

US3742253

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '30 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 16:02:33

US3742253

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Nov 2020 16:02:33

US3742253

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	19 Nov 2020 16:02:33

US3742253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 16:02:37

US3742253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 16:02:37

US3742253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 16:02:37

US3742253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 16:02:37

US3742253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 16:02:37

US3742253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 16:02:37

US3742253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 16:02:37

US3742253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

Pulse (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 16:02:37

US3742253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 16:02:37

US3742253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 16:02:37

US3742253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 16:02:37

US3742253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 16:02:37

US3742253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 16:02:37

US3742253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 16:02:37

US3742253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 16:02:37

US3742253

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 16:02:51

US3742253

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 16:02:51

US3742253

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 16:03:03

US3742253

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '30 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 16:03:03

US3742253

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '11:54'	(b) (4), (b) (6)	19 Nov 2020 16:03:03

US3742253

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '30 Oct 2020 11:54'	System	19 Nov 2020 16:03:03

US3742253

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 16:03:09

US3742253

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 16:03:09

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 64'	System	04 Sep 2020 15:35:06

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-11-06T14:58:58', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '00b28e40-29a6-4bab-b4b5-a5a277cc734d' User entered 'Yes (Y)'	System	06 Nov 2020 19:59:19
	System	06 Nov 2020 19:59:19

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Have you been exposed to someone with 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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-11-06T14:59:05', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '00b28e40-29a6-4bab-b4b5-a5a277cc734d'	System	06 Nov 2020 19:59:19
User entered 'No (N)'	System	06 Nov 2020 19:59:19

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-11-06T14:59:08', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '00b28e40-29a6-4bab-b4b5-a5a277cc734d'	System	06 Nov 2020 19:59:19
User entered 'No (N)'	System	06 Nov 2020 19:59:19

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-11-06T14:59:12', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '00b28e40-29a6-4bab-b4b5-a5a277cc734d'	System	06 Nov 2020 19:59:19
User entered 'No (N)'	System	06 Nov 2020 19:59:19

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-11-06T14:59:15', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '00b28e40-29a6-4bab-b4b5-a5a277cc734d' User entered '06 Nov 2020 14:59:15'	System	06 Nov 2020 19:59:19
	System	06 Nov 2020 19:59:19

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 15:35:06

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 71'	System	04 Sep 2020 15:35:06

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-11-11T22:29:12', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'c3431408-aa7f-487f-8622-092d5e8d2df0'	System	12 Nov 2020 03:29:24
User entered 'No (N)'	System	12 Nov 2020 03:29:24

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Have you been exposed to someone with 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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-11-11T22:29:17', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'c3431408-aa7f-487f-8622-092d5e8d2df0'	System	12 Nov 2020 03:29:24
User entered 'No (N)'	System	12 Nov 2020 03:29:24

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-11-11T22:29:21', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: 'c3431408-aa7f-487f-8622-092d5e8d2df0'	System	12 Nov 2020 03:29:24
User entered '11 Nov 2020 22:29:21'	System	12 Nov 2020 03:29:24

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 15:35:06

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered 'Day 78'	System	04 Sep 2020 15:35:06

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-11-18T05:51:12', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '50173889-7d1a-4b67-801c-ffcf6e9f9f9f'	System	18 Nov 2020 10:51:24
User entered 'No (N)'	System	18 Nov 2020 10:51:24

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

Have you been exposed to someone with 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 (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-11-18T05:51:18', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '50173889-7d1a-4b67-801c-ffcf6e9f9f9f'	System	18 Nov 2020 10:51:24
User entered 'No (N)'	System	18 Nov 2020 10:51:24

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (913530A2-21CC-44F0-8DFA-713FE93D3188)', Time: '2020-11-18T05:51:22', User OID: 'PatientReportedOutcome (US3742253)', ODM File OID: '50173889-7d1a-4b67-801c-ffcf6e9f9f9f' User entered '18 Nov 2020 05:51:22'	System	18 Nov 2020 10:51:24
	System	18 Nov 2020 10:51:24

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 15:35:06

US3742253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 15:35:06
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 15:35:06

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '01 Nov 2020 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '05 Nov 2020 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '08 Nov 2020 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '12 Nov 2020 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '15 Nov 2020 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '19 Nov 2020 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:47:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:47:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:47:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:47:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:47:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:47:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:47:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 03:47:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:47:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:47:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:47:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:47:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:47:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:47:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 03:47:56

US3742253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:47:56
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 03:47:56

US3742253

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Nov 2020 16:57:37
	(b) (4)	

US3742253

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Sherry McCammon (b) (4)	23 Nov 2020 16:57:37
	(b) (4)	

US3742253

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	23 Nov 2020 16:57:37

US3742253

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	23 Nov 2020 16:57:37
	(b) (4)	

US3742253

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Nov 2020 16:57:44
	(b) (4)	

US3742253

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 16:57:44

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:12:49

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:02
User entered '25 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 17:31:07

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:12:49

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:02
User entered '08:48'	(b) (4), (b) (6)	26 Sep 2020 17:31:07

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:12:49

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 08:48'	System	26 Sep 2020 17:31:07

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:12:49

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:02
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	26 Sep 2020 17:31:07

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:12:49

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 17:31:07

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered '20 Sep 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00
User entered '25 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered '1' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00
User entered '98'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 19:37:00
User entered '%'	System	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00
User entered '98.6' F	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'Mild (Mild)' reason for change: New Information	Hassan Haji (b) (4)	05 Oct 2020 19:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'Mild (Mild)' reason for change: New Information	Hassan Haji (b) (4)	05 Oct 2020 19:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'Mild (Mild)' reason for change: New Information	Hassan Haji (b) (4)	05 Oct 2020 19:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: New Information	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00
User entered 'Mild (Mild)' reason for change: New Information	Hassan Haji (b) (4)	05 Oct 2020 19:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: New Information	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00
User entered 'Mild (Mild)' reason for change: New Information	Hassan Haji (b) (4)	05 Oct 2020 19:56:05
User entered 'None (None)'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:12:49

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)'	(b) (4), (b) (6)	26 Sep 2020 17:35:46

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)' reason for change:	Sherry McCammon	(b) (4) 13 Oct 2020 19:39:10
Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon	(b) (4) 13 Oct 2020 19:37:00
	(b) (4)	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 19:39:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 19:39:10
User entered '21 Sep 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:39:10
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 19:37:00
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered '1' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
User entered '0'	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00
	(b) (4)	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 19:37:00

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00
	(b) (4)	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:39:10
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:39:10
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:39:10
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:39:10
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:39:10
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:39:10
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:39:10
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:39:10
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:39:10
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:39:10
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:39:10
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:39:10
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:39:10
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:39:10
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:39:10
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:49

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:39:10
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:37:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Form: Symptom Log (3)

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[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered '25 Sep 2020'	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered '0'	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered '98'	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Oct 2020 19:41:46

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered '098.6' F	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:46:25
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:46:25
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:46:25
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:46:25
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
DataPoint Un-verified.	Sherry McCammon (b) (4)	29 Oct 2020 16:57:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:57:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:46:25
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:46:25
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:46:25
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:46:25
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:46:25
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:46:25
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:46:25
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:46:25
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:46:25
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:46:25
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:46:25
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:49

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:27:48
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:46:25
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 19:41:46

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20
	(b) (4)	

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Form: Symptom Log (4)

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[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '26 Sep 2020'	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '0'	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:51:09
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20
	(b) (4)	

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Form: Symptom Log (4)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	29 Oct 2020 16:51:09
User entered empty.	System	29 Oct 2020 16:48:20

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '97.2' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:53:52
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:55:24
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:54:52
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:57:52
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:56:37
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:00:59
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:00:59
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:02:07
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:02:07
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:02
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:02
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:44
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:44
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:49

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:04:40
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:20
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

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[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '27 Oct 2020'	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '0'	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:51:09
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32
	(b) (4)	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	29 Oct 2020 16:51:09
User entered empty.	System	29 Oct 2020 16:48:32

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '97.3' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:53:52
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:55:24
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32
	(b) (4)	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:54:52
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:57:52
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32
	(b) (4)	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:56:37
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32
	(b) (4)	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:00:59
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32
	(b) (4)	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:00:59
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32
	(b) (4)	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:02:07
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:02:07
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32
	(b) (4)	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:02
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:02
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32
	(b) (4)	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:44
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:04:40
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:49

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:04:40
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '28 Oct 2020'	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '0'	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:51:09
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	29 Oct 2020 16:51:09
User entered empty.	System	29 Oct 2020 16:48:52

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '97.0' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:53:52
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:55:24
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:54:52
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:57:52
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52
	(b) (4)	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:56:37
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:00:59
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:00:59
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:02:07
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:02:07
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:02
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:02
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:44
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:04:40
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:49

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:04:40
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:48:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '29 Sep 2020'	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '0'	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:51:09
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	29 Oct 2020 16:51:09
User entered empty.	System	29 Oct 2020 16:49:32

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '97.0' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:53:52
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:55:24
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:54:52
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:57:52
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:56:37
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:00:59
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:00:59
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:02:07
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:02:07
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:02
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:02
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:44
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:04:40
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:49

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:04:40
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:49:32

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '30 Sep 2020'	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '0'	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:51:09
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	29 Oct 2020 16:51:09
User entered empty.	System	29 Oct 2020 16:50:00

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '97.3' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:53:52
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:55:24
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:54:52
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:57:52
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:56:37
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:00:59
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:00:59
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:02:07
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:02:07
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:02
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:02
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:04:59
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 17:03:44
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:04:40
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:49

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:04:40
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:00

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '01 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:50:51
User entered '1 Oct 2020'	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '0'	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:51:09
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	29 Oct 2020 16:51:09
User entered empty.	System	29 Oct 2020 16:50:13

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '96.8' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:53:52
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:55:24
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:54:52
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:57:52
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:56:37
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 16:59:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:00:59
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:00:59
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:02:07
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:02:07
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:02
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:02
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:03:44
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:04:40
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:49

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	29 Oct 2020 17:04:40
User entered empty.	Sherry McCammon (b) (4)	29 Oct 2020 16:50:13

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '02 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:50:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Oct 2020 19:40:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 19:40:38
User entered '2 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Oct 2020 19:39:59
User entered empty.	System	30 Oct 2020 19:39:59
	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '0'	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '99' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:43:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59
	(b) (4)	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Oct 2020 19:43:17
User entered empty.	System	30 Oct 2020 19:39:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '97.8' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:48:22
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:50:51
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:51:55
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:51:55
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:52:40
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:52:40
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59
	(b) (4)	

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:53:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:53:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:53:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:54:48
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:54:48
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:54:48
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:56:29
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:49

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:56:29
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:39:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '03 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:50:51
User entered '3 Oct 2020'	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '0'	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:43:17
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Oct 2020 19:43:17
User entered empty.	System	30 Oct 2020 19:40:38

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '97.2' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:48:22
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:50:51
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:51:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:51:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:52:40
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:52:40
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:53:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:53:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:53:45
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:54:48
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:54:48
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:54:48
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:56:29
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:49

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:56:29
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:40:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '04 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:50:51
User entered '4 Oct 2020'	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '0'	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:43:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Oct 2020 19:43:17
User entered empty.	System	30 Oct 2020 19:40:49

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '97.0' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:48:22
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:51:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:51:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:51:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:52:40
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:52:40
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:53:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:53:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:53:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:54:48
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:54:48
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:54:48
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:55:45
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:55:45
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:56:29
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:49

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:56:29
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:40:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)'	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '05 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:50:51
User entered '5 Oct 2020'	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '0'	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:43:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Oct 2020 19:43:17
User entered empty.	System	30 Oct 2020 19:41:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '94.2' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:48:22
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:51:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:51:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:51:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:52:40
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:52:40
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:53:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:53:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:53:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:54:48
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:54:48
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:54:48
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:55:45
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:56:29
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:49

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:56:29
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 17 (Day 17)'	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25
	(b) (4)	

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Form: Symptom Log (14)

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[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '06 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:50:51
User entered '6 Oct 2020'	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '0'	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:43:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Oct 2020 19:43:17
User entered empty.	System	30 Oct 2020 19:41:25

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '97.2' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:48:22
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:51:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:51:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:51:55
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:52:40
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:52:40
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:53:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:53:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:53:45
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:54:48
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:54:48
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:54:48
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:56:29
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:49

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:56:29
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:25

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 18 (Day 18)'	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Form: Symptom Log (15)

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[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '07 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:50:51
User entered '7 Oct 2020'	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '0'	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:43:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Oct 2020 19:43:17
User entered empty.	System	30 Oct 2020 19:41:40

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '97.2' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:48:22
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
DataPoint Un-verified.	Sherry McCammon (b) (4)	19 Nov 2020 16:15:09
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:15:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:15:09
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:15:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:15:09
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:15:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:15:09
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:15:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Form: Symptom Log (15)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Form: Symptom Log (15)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:49

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:41:40
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 19 (Day 19)'	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Form: Symptom Log (16)

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[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '08 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:50:51
User entered '8 Oct 2020'	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '0'	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:43:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Oct 2020 19:43:17
User entered empty.	System	30 Oct 2020 19:42:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered '97.0' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:48:22
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
DataPoint Un-verified.	Sherry McCammon (b) (4)	19 Nov 2020 16:15:09
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:15:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:15:09
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:15:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:15:09
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:15:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:15:09
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:15:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:16:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:12:49

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:44:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 13:48:15
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:17:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:08:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 19:42:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:12:49

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:25:52
User closed query 'Please confirm response as data is discrepant with visit date captured in Preclarus portal.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:25:23
Query 'Please confirm response as data is discrepant with visit date captured in Preclarus portal.' answered with 'visit was sept 25th and positive result was october 3rd' (Site from CRA).	Kaitlin Mason (b) (4)	21 Oct 2020 12:44:51
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 12:44:42
User opened query 'Please confirm response as data is discrepant with visit date captured in Preclarus portal.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 22:16:40
User entered '3 Oct 2020'	Hassan Haji (b) (4)	05 Oct 2020 19:48:14

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:12:49

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:25:52
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	05 Oct 2020 19:48:14

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:12:49

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 05:05:41
User closed query 'Please confirm response as data is discrepant with testing collected 25Sep2020 and resulted 03Oct2020.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:25:52
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 'Result was positive ' (Site from System).	Kaitlin Mason (b) (4)	23 Oct 2020 14:25:40
Query 'Please confirm response as data is discrepant with testing collected 25Sep2020 and resulted 03Oct2020.' answered with 'subject tested positive' (Site from CRA).	Kaitlin Mason (b) (4)	21 Oct 2020 12:45:26
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	21 Oct 2020 12:45:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	21 Oct 2020 12:44:42
User opened query 'Please confirm response as data is discrepant with testing collected 25Sep2020 and resulted 03Oct2020.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 12:44:42
User entered 'No (N)'	Hassan Haji (b) (4)	19 Oct 2020 22:13:34
	(b) (4)	05 Oct 2020 19:48:14

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Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

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[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:25:52
User closed query 'Please confirm date of central lab testing as response is discrepant with data captured in Preclarus portal.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:25:47
Query 'Please confirm date of central lab testing as response is discrepant with data captured in Preclarus portal.' answered with 'date of testing was sept 25, result was october 3rd' (Site from CRA).	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 12:45:44
User entered '25 Sep 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 12:44:42
User opened query 'Please confirm date of central lab testing as response is discrepant with data captured in Preclarus portal.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 22:15:43
User entered '3 Oct 2020'	Hassan Haji (b) (4) (b) (4)	05 Oct 2020 19:48:14

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Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:12:49

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:25:52
User entered 'Nasal Swab (Nasal Swab)'	Hassan Haji (b) (4) (b) (4)	05 Oct 2020 19:48:14

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Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

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[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:25:52
User entered empty.	Hassan Haji (b) (4) (b) (4)	05 Oct 2020 19:48:14

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Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:12:49

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:25:52
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	05 Oct 2020 19:49:49
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	05 Oct 2020 19:48:14
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	05 Oct 2020 19:48:14

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Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:25:52
User entered empty.	Hassan Haji (b) (4) (b) (4)	05 Oct 2020 19:48:14

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Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:12:49

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:25:52
User entered empty; reason for change Data Entry Error	Hassan Haji (b) (4) (b) (4)	05 Oct 2020 19:49:49
User entered 'No (N)' reason for change: Data Entry Error	Hassan Haji (b) (4) (b) (4)	05 Oct 2020 19:48:44
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	05 Oct 2020 19:48:14

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Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:12:49

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 12:44:42
User entered '0'	System	05 Oct 2020 19:48:14

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

Did the subject have Respiratory Rates $\geq$ 30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

Did the subject have Oxygen Saturation of $\text{SpO}_2 \leq 93\%$ on room air at sea level?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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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)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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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)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 15:58:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 15:58:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 15:58:18
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 15:58:04
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:49

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:42:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:58:04

US3742253

Folder: Covid-19 Assessment 25 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:12:49

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:28:18
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	05 Oct 2020 19:50:15

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:12:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 12:51:50

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:12:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:29:05
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	21 Oct 2020 12:51:50
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:12:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:29:05
User entered '27 Sep 2020'	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 12:51:50

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:12:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 12:51:50

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:12:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:29:05
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 12:51:50

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:12:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:29:05
User entered '29 Sep 2020'	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 12:51:50

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:12:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 12:51:50

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:12:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:29:05
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 12:51:50

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:12:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:29:05
User entered '01 Oct 2020'	Kaitlin Mason (b) (4)	21 Oct 2020 12:51:50
	(b) (4)	

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:12:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 12:51:50

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:12:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:29:05
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	21 Oct 2020 12:51:50
	(b) (4)	

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:12:49

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03OCT2020 is recorded under Illness Visit Day9 visit in EDC, however the same is reported with date 05OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:11:43
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03OCT2020 is recorded under Illness Visit Day9 visit in EDC, however the same is reported with date 05OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'Confirming Day 9 is 03OCT2020' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:40:47
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03OCT2020 is recorded under Illness Visit Day9 visit in EDC, however the same is reported with date 05OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:40:16
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:29:05
User entered '03 Oct 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	21 Oct 2020 12:53:45
User entered '08 Oct 2020'	Kaitlin Mason (b) (4)	21 Oct 2020 12:51:50

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:12:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 12:51:50

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:12:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:29:05
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	21 Oct 2020 12:51:50
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:12:49

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08OCT2020 is recorded under Illness Visit Day14 visit in EDC, however the same is reported with date 09OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:12:40
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08OCT2020 is recorded under Illness Visit Day14 visit in EDC, however the same is reported with date 09OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'Confirming 08OCT2020 is Day 14' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:41:13
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08OCT2020 is recorded under Illness Visit Day14 visit in EDC, however the same is reported with date 09OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:41:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:29:05
User entered '08 Oct 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	21 Oct 2020 12:53:45
User entered '15 Oct 2020'	Kaitlin Mason (b) (4)	21 Oct 2020 12:51:50

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:12:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 12:51:50

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:12:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:29:05
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 12:53:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 12:53:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	21 Oct 2020 12:53:45
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 12:51:50
User entered empty.	Kaitlin Mason (b) (4)	21 Oct 2020 12:51:50

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:12:49

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: GCL has Saliva Day 21 with date of 01OCT2020. Please reconcile and clarify' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:14:00
Query 'Per GCL Lab Recon: GCL has Saliva Day 21 with date of 01OCT2020. Please reconcile and clarify' answered with 'Day 7 collected in Day 21 vail, PPD aware' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:42:17
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:29:05
User opened query 'Per GCL Lab Recon: GCL has Saliva Day 21 with date of 01OCT2020. Please reconcile and clarify' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 13:00:05
User entered '15 Oct 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	21 Oct 2020 12:53:45
User entered empty.	Kaitlin Mason (b) (4)	21 Oct 2020 12:51:50

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:12:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 12:51:50

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:12:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:43:20
DataPoint Un-verified.	Sherry McCammon (b) (4)	19 Nov 2020 16:18:49
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 16:18:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 13:29:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 06:34:15
Query 'Data is required. Please complete.' answered with 'Participant is due for visit tomorrow ' (Site from System).	Kaitlin Mason (b) (4)	21 Oct 2020 12:54:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 12:51:50
User entered empty.	Kaitlin Mason (b) (4)	21 Oct 2020 12:51:50
	(b) (4)	

US3742253

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:12:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:29:05
User entered empty.	Kaitlin Mason (b) (4)	21 Oct 2020 12:51:50
	(b) (4)	

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:12:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08
	(b) (4)	

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:12:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:55
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:32:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 16:32:04
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:32:04
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:26:35
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:26:35
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:12:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:55
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:26:35
User entered '27 Sep 2020'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:12:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08
	(b) (4)	

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:12:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:55
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:32:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 16:32:04
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:32:04
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:26:35
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:26:35
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:12:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:55
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:26:35
User entered '29 Sep 2020'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:12:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08
	(b) (4)	

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:12:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:55
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:32:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 16:32:04
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:32:04
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:26:35
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:26:35
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:12:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:55
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:26:35
User entered '1 Oct 2020'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:12:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:12:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:55
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:32:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 16:32:04
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:32:04
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:26:52
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:26:52
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:12:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:55
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:26:35
User entered '2 Oct 2020'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:12:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:12:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:55
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:32:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 16:32:04
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:32:04
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:26:52
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:26:52
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:34:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 19:34:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:34:19
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:34:08
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:12:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:55
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:26:35
User entered '8 Oct 2020'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:12:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:12:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:55
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:32:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 16:32:04
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:32:04
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:26:52
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:26:52
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:34:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 19:34:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:34:19
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:34:08
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:12:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:55
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:26:35
User entered '15 Oct 2020'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:12:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08
	(b) (4)	

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:12:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:55
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:32:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 16:32:04
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:32:04
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:26:52
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 16:26:52
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Oct 2020 19:34:19
User entered 'NA (COVID-19 Negative) (NA)'	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08

US3742253

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:12:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:55
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:34:08
	(b) (4)	

US3742253

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Data updated on Saliva Collection form of Illness visit 1 and Illness Visit 2 have Saliva collected in the Same Timeframe 27Sep2020- 15Oct2020. Please review and if duplicate then amend to avoid duplication.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:14:55
Query 'Per GCL Lab Reconciliation: Saliva: Data updated on Saliva Collection form of Illness visit 1 and Illness Visit 2 have Saliva collected in the Same Timeframe 27Sep2020- 15Oct2020. Please review and if duplicate then amend to avoid duplication.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	09 Nov 2020 16:08:33
User opened query 'Per GCL Lab Reconciliation: Saliva: Data updated on Saliva Collection form of Illness visit 1 and Illness Visit 2 have Saliva collected in the Same Timeframe 27Sep2020- 15Oct2020. Please review and if duplicate then amend to avoid duplication.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:33:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:27:13
User closed query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:27:10
Query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' answered with 'added' (Site from CRA).	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 12:54:25
User opened query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 20:35:34
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 12:51:55

US3742253

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:27:13
User entered '25 Sep 2020'	Sherry McCammon (b) (4)	30 Sep 2020 12:51:55
	(b) (4)	

US3742253

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:27:13
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 12:51:55

US3742253

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	30 Sep 2020 12:51:55

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:02
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Sep 2020 12:56:41
	(b) (4)	

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:02
User entered '25 Sep 2020'	Sherry McCammon (b) (4)	30 Sep 2020 12:56:41
	(b) (4)	

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:02
User entered '15:00'	Sherry McCammon (b) (4)	30 Sep 2020 12:56:41
	(b) (4)	

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '25 Sep 2020 15:00'	System	30 Sep 2020 12:56:41

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:02
User entered '059' in	Sherry McCammon (b) (4)	30 Sep 2020 12:56:41
DataPoint set to visible.	(b) (4) System	30 Sep 2020 12:51:55

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:02
User entered '171.6' lb	Sherry McCammon (b) (4)	30 Sep 2020 12:56:41
DataPoint set to visible.	(b) (4) System	30 Sep 2020 12:51:55

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:02
User entered '098.6' F	Sherry McCammon (b) (4)	30 Sep 2020 12:56:41
	(b) (4)	

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:02
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	30 Sep 2020 12:56:41
	(b) (4)	

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:02
User entered empty.	Sherry McCammon (b) (4)	30 Sep 2020 12:56:41
	(b) (4)	

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:02
User entered '077'	Sherry McCammon (b) (4)	30 Sep 2020 12:56:41
	(b) (4)	

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Sep 2020 12:56:41

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:02
User entered '16'	Sherry McCammon (b) (4)	30 Sep 2020 12:56:41
	(b) (4)	

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Sep 2020 12:56:41

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:02
User entered '108'	Sherry McCammon (b) (4)	30 Sep 2020 12:56:41
	(b) (4)	

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 12:56:41

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:02
User entered '080'	Sherry McCammon (b) (4)	30 Sep 2020 12:56:41
	(b) (4)	

US3742253

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 12:56:41

US3742253

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:29:52
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Sep 2020 12:53:38
	(b) (4)	

US3742253

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:29:52
User entered '25 Sep 2020'	Sherry McCammon (b) (4)	30 Sep 2020 12:53:38
	(b) (4)	

US3742253

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:12:49

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:29:40
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 13:07:22

US3742253

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:12:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:29:40
User entered '25 Sep 2020'	Sherry McCammon (b) (4)	30 Sep 2020 13:07:22
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:34
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	09 Nov 2020 16:28:45

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:34
User entered '30 Oct 2020'	Sherry McCammon (b) (4)	09 Nov 2020 16:28:45
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[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 17:49:34
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	09 Nov 2020 16:28:45
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	09 Nov 2020 16:28:45

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:41
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Nov 2020 16:28:56
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:41
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 16:28:56
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:41
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 16:28:56
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:28:56

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:41
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 16:28:56
DataPoint set to visible.	(b) (4) System	30 Oct 2020 19:35:10

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:41
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 16:28:56
DataPoint set to visible.	(b) (4) System	30 Oct 2020 19:35:10

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:41
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 16:28:56
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:41
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 16:28:56
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:41
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 16:28:56
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:41
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 16:28:56
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:28:56

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:41
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 16:28:56
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:28:56

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:41
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 16:28:56
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:28:56

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:41
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 16:28:56
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:28:56

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:48
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	09 Nov 2020 16:29:31
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:48
User entered '30 Oct 2020'	Sherry McCammon (b) (4)	09 Nov 2020 16:29:31
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:12:49

[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 17:49:54
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	09 Nov 2020 16:31:06
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:12:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:54
User entered '30 Oct 2020'	Sherry McCammon (b) (4)	09 Nov 2020 16:31:06
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:54:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Oct 2020 19:35:10
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:54:10
User entered '30 Oct 2020'	Sherry McCammon (b) (4)	30 Oct 2020 19:35:10
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[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 17:54:10
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4) (b) (4)	30 Oct 2020 19:35:10

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:49

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	30 Oct 2020 19:35:10

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:47
User entered 'No (N)'	Sherry McCammon (b) (4)	30 Oct 2020 19:35:15
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:47
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:35:15
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:47
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:35:15
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 19:35:15

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:47
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:35:15
DataPoint set to visible.	(b) (4) System	30 Oct 2020 19:35:10

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:47
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:35:15
DataPoint set to visible.	(b) (4) System	30 Oct 2020 19:35:10

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:47
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:35:15
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:47
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:35:15
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:47
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:35:15
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:47
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:35:15
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 19:35:15

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:47
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:35:15
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 19:35:15

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:47
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:35:15
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 19:35:15

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:47
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 19:35:15
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 19:35:15

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:54
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Oct 2020 19:36:05
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:54
User entered '30 Oct 2020'	Sherry McCammon (b) (4)	30 Oct 2020 19:36:05
	(b) (4)	

US3742253

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:12:49

[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 17:51:00
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	30 Oct 2020 19:35:54

US3742253

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:12:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:51:00
User entered '30 Oct 2020'	Sherry McCammon (b) (4)	30 Oct 2020 19:35:54
	(b) (4)	

US3742253

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:12:49

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:56
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	05 Oct 2020 20:08:19

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:29
User entered 'USA-US127-2020-mRNA-1273-P301000004'	System	14 Oct 2020 13:17:03
User entered 'New'	(b) (4), (b) (6)	14 Oct 2020 13:17:03

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Since the subject tested positive for COVID-19, please consider updating the event term to "COVID-19".' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 19:46:21
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
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)	27 Oct 2020 14:16:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 14:16:35
Data point term sent to Coder	System	27 Oct 2020 14:15:57
Query 'PV Query: Since the subject tested positive for COVID-19, please consider updating the event term to "COVID-19".' answered with 'Data changed.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:15:19
Coding entries removed.	(b) (4), (b) (6)	27 Oct 2020 14:15:08
User entered 'COVID-19' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 14:15:08
User opened query 'PV Query: Since the subject tested positive for COVID-19, please consider updating the event term to "COVID-19".' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 11:49:13
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)	08 Oct 2020 00:33:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 00:33:15
Data point term sent to Coder	System	07 Oct 2020 12:58:58
User entered 'COVID-LIKE ILLNESS'	Sherry McCammon (b) (4) (b) (4)	07 Oct 2020 12:58:50

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, please refer to protocol section 8.3.4 for the Solicited Adverse Reaction AE reporting criteria. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:18:35
Query 'Per DM CLR - RQ: Site's response noted. However, please refer to protocol section 8.3.4 for the Solicited Adverse Reaction AE reporting criteria. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'Updated as requested' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:02:15
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 15:01:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 15:01:48
User opened query 'Per DM CLR - RQ: Site's response noted. However, please refer to protocol section 8.3.4 for the Solicited Adverse Reaction AE reporting criteria. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:39:07
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:31:50
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'Confirming this was a solicited adverse reaction as symptoms were found during day 22 safety call ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:45:02

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 10:13:22
	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 19:50:11
User entered 'No (N)'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered '20 Sep 2020'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered empty.	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 12:58:50

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered 'No (N)'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: The end date is reported as 23 Sep 2020, however per the symptoms log, the subject reported symptoms of mild fatigue on 25 Sep 2020. Please consider updating the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 19:46:25
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
Query 'PV Query: The end date is reported as 23 Sep 2020, however per the symptoms log, the subject reported symptoms of mild fatigue on 25 Sep 2020. Please consider updating the event end date (when symptoms have resolved).' answered with 'Updated' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 17:58:57
User entered '29 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 17:58:50
User opened query 'PV Query: The end date is reported as 23 Sep 2020, however per the symptoms log, the subject reported symptoms of mild fatigue on 25 Sep 2020. Please consider updating the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 11:49:04
User entered '23 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	07 Oct 2020 12:58:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered empty.	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 12:58:50

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered 'No (N)'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered '0'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered '0'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered '0'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered empty.	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered empty.	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered empty.	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered empty.	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered '0'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered '0'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered '0'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

US3742253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 22:47:59
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 'investigational product withdrawn due to SARS-COV-2. SAE is also COVID19 infection but the drop down box for covid19 infection is the most accurate description. If dosing discontinuation can only be due to AE or SAE please specify ' (Site from System).	Kaitlin Mason (b) (4) (b) (4)	09 Nov 2020 16:07:36
User closed query 'Per CDM Re-query: Please complete Dosing Discontinuation Form as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:07:19
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	02 Nov 2020 19:26:51
Query 'Per CDM Re-query: Please complete Dosing Discontinuation Form as appropriate. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 18:55:57
User opened query 'Per CDM Re-query: Please complete Dosing Discontinuation Form as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:34:21
Query 'Per CDM Re-query: Please complete Dosing Continuation Form as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:34:12
User opened query 'Per CDM Re-query: Please complete Dosing Continuation Form as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:34:10
Query 'Per CDM Re-query: Please complete Dosing Continuation Form as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:34:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:33:56
User opened query 'Per CDM Re-query: Please complete Dosing Continuation Form as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:33:54
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' answered with 'Yes, participant did not receive second dose.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:46:01
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:13:32
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). DataPoint Un-verified.	System	06 Nov 2020 15:27:28
	(b) (4), (b) (6)	06 Nov 2020 15:27:28
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 15:27:28
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). DataPoint Verified.	System	06 Nov 2020 15:27:19
	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered '0' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	21 Oct 2020 14:06:43
	(b) (4)	
User entered '1'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 15:11:53
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'No medication taken, updated as requested' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:28:14
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 15:27:19
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 15:27:19
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:39:20
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	21 Oct 2020 14:06:43
User entered '0'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered '0'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User entered empty.	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:25:31
User closed query 'PV Query: It was reported the subject received Aspirin on 28 Sep 2020 due to COVID related hypercoagulability. Was this a prophylactic measure? If not, please provide more details.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 00:05:06
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 00:04:54
User closed query 'PV Query: Did the subject have any known COVID-19 exposures or contacts.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 00:04:46
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 00:04:30
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 00:04:09
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 00:03:59
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'Participant received Aspirin 81mg once daily po for prophylaxis of COVID associated hypercoagulability and vitamin C 2g once daily po for health maintenance ' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 12:42:15
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'Yes subject was tested and found to be positive ' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 12:41:00
v6.020 DTW (1102)		1826 of 1958

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' answered with 'will complete ' (Site from Safety).	Kaitlin Mason (b) (4)	21 Oct 2020 12:40:44
Query 'PV Query: Did the subject have any known COVID-19 exposures or contacts.' answered with 'Participant's wife was COVID positive on enrollment in the study. Suspected contact is children attending school who infected he and his wife. Son (9 yo) was positive for covid19' (Site from Safety).	Kaitlin Mason (b) (4)	21 Oct 2020 12:40:29
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Participant was tested for COVID 19 September 25 2020 and reported positive by PCR swab October 03 2020' (Site from Safety).	Kaitlin Mason (b) (4)	21 Oct 2020 12:36:00
Query 'PV Query: It was reported the subject received Aspirin on 28 Sep 2020 due to COVID related hypercoagulability. Was this a prophylactic measure? If not, please provide more details.' answered with 'Yes - measure for prophylaxis ' (Site from Safety).	Kaitlin Mason (b) (4)	21 Oct 2020 12:34:47
User opened query 'PV Query: It was reported the subject received Aspirin on 28 Sep 2020 due to COVID related hypercoagulability. Was this a prophylactic measure? If not, please provide more details.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:50:40
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:50:18
User opened query 'PV Query: Did the subject have any known COVID-19 exposures or contacts.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:50:10
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:49:18
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:49:06

v6.020 DTW (1102)

1827 of 1958

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:48:57
User entered empty.	Sherry McCammon (b) (4)	07 Oct 2020 12:58:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:49

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	07 Oct 2020 12:58:50

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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	07 Oct 2020 12:58:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:12:49

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:20:01
User closed query 'Per ETRTR: AE COVID page indicates no medication was dosed for COVID, but ConMeds are registered for COVID. Please update AE page to indicate Concomitant Medication was provided if applicable, thanks.' (Site from CRA). Query 'Per ETRTR: AE COVID page indicates no medication was dosed for COVID, but ConMeds are registered for COVID. Please update AE page to indicate Concomitant Medication was provided if applicable, thanks.' answered with 'added to ae information ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:19:59
User opened query 'Per ETRTR: AE COVID page indicates no medication was dosed for COVID, but ConMeds are registered for COVID. Please update AE page to indicate Concomitant Medication was provided if applicable, thanks.' (Site from CRA). User entered 'Yes (Y)' reason for change: New Information	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 12:55:07
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 20:31:11
	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:31:51
	Hassan Haji (b) (4) (b) (4)	04 Sep 2020 19:30:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 13:47:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 13:47:19
Data point term sent to Coder	System	02 Nov 2020 18:04:29
Coding entries removed.	(b) (4), (b) (6)	02 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:48:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:48:34
Data point term sent to Coder	System	09 Oct 2020 19:35:05
User entered 'aspirin'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:35:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:35:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis = YES. Please review Indication and please update to reflect the term Prophylaxis and the medical condition prevented. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 12:41:23
Query 'Per DM CLR: Prophylaxis = YES. Please review Indication and please update to reflect the term Prophylaxis and the medical condition prevented. Please update as appropriate or provide clarification.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 18:04:27
User entered 'PROPHYLAXIS of COVID-RELATED HYPERCOAGULABILITY' reason for change: Data Entry Error DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 18:04:12
	(b) (4), (b) (6)	02 Nov 2020 18:03:36
User entered 'Prophylaxis for COVID-RELATED HYPERCOAGULABILITY' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 18:03:36
User opened query 'Per DM CLR: Prophylaxis = YES. Please review Indication and please update to reflect the term Prophylaxis and the medical condition prevented. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:30:59
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered 'Covid related hypercoagulability'	Hassan Haji (b) (4)	09 Oct 2020 19:35:04
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered '81' reason for change: Data Entry Error	Hassan Haji (b) (4)	09 Oct 2020 19:37:58
User entered '80'	(b) (4)	
	Hassan Haji (b) (4)	09 Oct 2020 19:35:04
	(b) (4)	

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered 'mg (mg)'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:35:04

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:35:04

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered 'twice daily (BID)'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:35:04

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:35:04

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered 'Oral (ORAL)'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:35:04

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:35:04

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered '28 Sep 2020'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:35:04

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered '0'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:35:04

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:35:04

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:35:04

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:35:04

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Oct 2020 19:35:04

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:35:04

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Oct 2020 19:35:04

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:40:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:40:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
Data point term sent to Coder	System	27 Oct 2020 12:35:47
Coding entries removed.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 12:35:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 19:38:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 19:38:31
Data point term sent to Coder	System	09 Oct 2020 19:37:10
User entered 'vitamin C'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:36:19

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User closed query 'Per CDM: Prophylaxis is No, however; indication recorded suggests medication was given as a prophylaxis. Please review and update as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:45:12
Query 'Per CDM: Prophylaxis is No, however; indication recorded suggests medication was given as a prophylaxis. Please review and update as appropriate or clarify.' answered with 'UPDATED' (Site from DM).	Kaitlin Mason (b) (4)	26 Oct 2020 16:37:15
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 16:37:11
User opened query 'Per CDM: Prophylaxis is No, however; indication recorded suggests medication was given as a prophylaxis. Please review and update as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:20:50
User entered 'No (N)'	Hassan Haji (b) (4)	09 Oct 2020 19:36:19

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered 'HEALTH MAINTENANCE prophylaxis' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 12:35:05
User entered 'health maintenance'	(b) (4)	
	Hassan Haji (b) (4)	09 Oct 2020 19:36:19
	(b) (4)	

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered '2'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:36:19

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered 'g (g)'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:36:19

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:36:19

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered 'once daily (QD)'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:36:19

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:36:19

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered 'Oral (ORAL)'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:36:19

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:36:19

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered '28 Sep 2020'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:36:19

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered '0'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:36:19

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:36:19

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:36:19

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:26:43
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	09 Oct 2020 19:36:19

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:36:19

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:36:19

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Oct 2020 19:36:19

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:21
Data point term sent to Coder	System	23 Nov 2020 17:00:14
User entered 'INFLUENZA VACCINE'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 16:59:15

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Nov 2020 16:59:15
	(b) (4)	

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Indication](#)

Audit	User	Time (GMT)
User entered 'INFLUENZA PROPHYLAXIS'	Sherry McCammon (b) (4)	23 Nov 2020 16:59:15

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	Sherry McCammon (b) (4)	23 Nov 2020 16:59:15
	(b) (4)	

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	Sherry McCammon (b) (4)	23 Nov 2020 16:59:15
	(b) (4)	

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	23 Nov 2020 16:59:15
	(b) (4)	

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Sherry McCammon (b) (4)	23 Nov 2020 16:59:15
	(b) (4)	

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	23 Nov 2020 16:59:15
	(b) (4)	

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Sherry McCammon (b) (4)	23 Nov 2020 16:59:15

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	23 Nov 2020 16:59:15
	(b) (4)	

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User entered '07 Nov 2020'	Sherry McCammon (b) (4)	23 Nov 2020 16:59:15
	(b) (4)	

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	23 Nov 2020 16:59:15
	(b) (4)	

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	23 Nov 2020 16:59:15
	(b) (4)	

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '07 Nov 2020'	Sherry McCammon (b) (4)	23 Nov 2020 16:59:15
	(b) (4)	

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	23 Nov 2020 16:59:15
	(b) (4)	

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 16:59:15

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 16:59:15

US3742253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 16:59:15

US3742253

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:12:49

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '3 Oct 2020'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:26:51

US3742253

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:12:49

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'Due to SARS-COV-2 (COVID)'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:26:51

US3742253

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:12:49

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

Audit	User	Time (GMT)
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	06 Nov 2020 15:05:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 15:05:16
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	06 Nov 2020 15:04:25
User entered 'Adverse event - COVID 19' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 15:04:25
User entered empty.	Hassan Haji (b) (4)	02 Nov 2020 19:26:51
	(b) (4)	

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'USA-US127-2020-MRNA-1273-P301000004'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'Karen'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'Kotloff'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered '685 W. Baltimore Street, HSF 480'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'Baltimore'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:08:58
Un-reviewed for Safety.	System	23 Oct 2020 00:08:18
User entered empty.	System	23 Oct 2020 00:08:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:07:52
User entered 'Maryland'	Kaitlin Mason (b) (4)	21 Oct 2020 12:46:54
	(b) (4)	

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered '21201'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:07:52
User entered 'US'	System	14 Oct 2020 13:17:48

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Oct 2020 19:46:43
User entered '2'	System	23 Oct 2020 00:08:18
User entered '1'	System	14 Oct 2020 13:17:48

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'USA-US127-2020-MRNA-1273-P301000004'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'Karen'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'Kotloff'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered '685 W. Baltimore Street, HSF 480'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'Baltimore'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:08:58
Un-reviewed for Safety.	System	23 Oct 2020 00:08:18
User entered empty.	System	23 Oct 2020 00:08:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:07:52
User entered 'Maryland'	Kaitlin Mason (b) (4)	21 Oct 2020 12:46:54
	(b) (4)	

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered '21201'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:07:52
User entered 'US'	System	14 Oct 2020 13:17:48

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Oct 2020 19:46:43
User entered '2'	System	23 Oct 2020 00:08:18
User entered '1'	System	14 Oct 2020 13:17:48

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:12:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
User entered '14/Oct/2020 09:17'	System	14 Oct 2020 13:17:48

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:12:49

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)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:07:52
User entered '1'	(b) (4), (b) (6)	14 Oct 2020 13:17:48

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'USA-US127-2020-MRNA-1273-P301000004'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'Karen'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'Kotloff'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered '685 W. Baltimore Street, HSF 480'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'Baltimore'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:08:58
Un-reviewed for Safety.	System	23 Oct 2020 00:08:18
User entered empty.	System	23 Oct 2020 00:08:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:07:52
User entered 'Maryland'	Kaitlin Mason (b) (4)	21 Oct 2020 12:46:54
	(b) (4)	

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered '21201'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:07:52
User entered 'US'	System	14 Oct 2020 13:17:48

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Oct 2020 19:46:43
User entered '2'	System	23 Oct 2020 00:08:18
User entered '1'	System	14 Oct 2020 13:17:48

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:12:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
User entered '23/Oct/2020 00:08'	System	23 Oct 2020 00:08:18

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:12:49

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)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:08:58
User entered '1'	(b) (4), (b) (6)	23 Oct 2020 00:08:18

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'USA-US127-2020-MRNA-1273-P301000004'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

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Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'No (N)'	System	14 Oct 2020 13:17:03

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Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'Karen'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'Kotloff'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

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Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered '685 W. Baltimore Street, HSF 480'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered 'Baltimore'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:08:58
Un-reviewed for Safety.	System	23 Oct 2020 00:08:18
User entered empty.	System	23 Oct 2020 00:08:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:07:52
User entered 'Maryland'	Kaitlin Mason (b) (4)	21 Oct 2020 12:46:54
	(b) (4)	

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Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:17:41
User entered '21201'	System	14 Oct 2020 13:17:03

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 13:30:49
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:07:52
User entered 'US'	System	14 Oct 2020 13:17:48

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Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Oct 2020 19:46:43
User entered '2'	System	23 Oct 2020 00:08:18
User entered '1'	System	14 Oct 2020 13:17:48

US3742253

Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:12:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:53:55
User entered '28/Oct/2020 19:46'	System	28 Oct 2020 19:46:43

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Folder: SAE USA-US127-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:12:49

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 17:53:55
User entered '1'	(b) (4), (b) (6)	28 Oct 2020 19:46:43