

US3252075 (Prod: Centex Studies Inc)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:49:12

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US3252075

Form: Participant Creation

Generated On: 26 Nov 2020 10:49:12

[Participant ID](#)

US3252075

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:49:12

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:49:12

Date of Informed Consent (<i>dd MMM yyyy</i>)	7 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:49:12

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:49:12

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:49:12

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:49:12

Condition	RIGHT HIP REPLACEMENT
Start date (dd MMM yyyy)	UN JAN 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JAN 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	07 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:20 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 12:20
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	165.8 lb
BMI (<i>xxx.x</i>)	27.64825 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

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

Generated On: 26 Nov 2020 10:49:12

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 10:49:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:49:12

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

What was the participant's randomization number? 185139

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:49:12

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 10:49:12

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	12:20 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 12:20
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	14:27 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 14:27
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

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) 07 AUG 2020

What was the treatment time? (00:00-23:59) 13:37 (24 HR)

Treatment Date and Time (derived) 07 AUG 2020 13:37

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 10:49:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	07 AUG 2020
Collection time (<i>00:00-23:59</i>)	12:58 (24 HR)
Collection date and time (derived)	07 AUG 2020 12:58

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:49:12

Collection date (<i>dd MMM yyyy</i>)			07 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:54	07 AUG 2020 12:54
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

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 10:49:12

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

98.3 °F

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

Yes ☐
No ☒

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

PC Time Stamp 07 AUG 2020 14:42

PC Open Date & Time 07 AUG 2020 13:57

PC Close Date & Time 07 AUG 2020 16:27

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 17:23

PC Open Date & Time

07 AUG 2020 17:22

PC Close Date & Time

08 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 14:36

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 12:03

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:49:12

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 13:02

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:49:12

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 13:30

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 13:31

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

13 AUG 2020 12:00

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 14:41

PC Open Date & Time

07 AUG 2020 13:57

PC Close Date & Time

07 AUG 2020 16:27

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 17:24

PC Open Date & Time

07 AUG 2020 17:22

PC Close Date & Time

08 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 14:37

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 12:04

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 13:02

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 13:30

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 13:32

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 12:01

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 14:42
PC Open Date & Time	07 AUG 2020 13:57
PC Close Date & Time	07 AUG 2020 16:27

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 17:25
PC Open Date & Time	07 AUG 2020 17:22
PC Close Date & Time	08 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:49:12

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 ☒

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:49:12

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 14:38
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:49:12

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 ☒

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:49:12

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 12:05
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:49:12

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 ☒

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:49:12

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 13:03
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:49:12

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 ☒

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:49:12

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 13:31
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:49:12

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 ☒

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:49:12

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 13:33
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:49:12

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 ☒

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:49:12

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 12:02
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3252075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252075

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 SEP 2020
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 13:10
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3252075

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

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.

US3252075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

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? _____

US3252075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:49:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	12 SEP 2020
Collection time (<i>00:00-23:59</i>)	13:14 (24 HR)
Collection date and time (derived)	12 SEP 2020 13:14

US3252075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:49:12

Collection date (dd MMM yyyy)			12 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:21	12 SEP 2020 13:21
Nasopharyngeal Swab 2	No		

US3252075

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

Was Contact Attempted?

Yes ☒

No ☐

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

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252075

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

Was Contact Attempted?

Yes ☒

No ☐

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

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252075

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

Was Contact Attempted?

Yes ☒

No ☐

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

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252075

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252075

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	VISIT3

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:57 (24 HR)
Vital Signs Date and Time (derived)	10 OCT 2020 12:57
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252075

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

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.

US3252075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:49:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	10 OCT 2020
Collection time (<i>00:00-23:59</i>)	13:21 (24 HR)
Collection date and time (derived)	10 OCT 2020 13:21

US3252075

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

15 OCT 2020 12:49:16

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 07:49:25

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 07:34:26

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 OCT 2020 00:01
Patient Cloud Close Date & Time	08 OCT 2020 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	18 OCT 2020 00:01
Patient Cloud Close Date & Time	22 OCT 2020 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

Date and time of submission

19 NOV 2020 18:20:38

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 19:36:39

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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03 FEB 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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10 FEB 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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13 FEB 2022 00:01

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17 FEB 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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24 FEB 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

Date and time of submission

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27 FEB 2022 00:01

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03 MAR 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

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10 MAR 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 MAR 2022 00:01
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US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

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24 MAR 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

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31 MAR 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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07 APR 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3252075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 NOV 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

PATIENT DID NOT ANSWER
PHONE CALL, TEXT OR EMAIL.

If Contact Not Made, please provide Comments

US3252075

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252075

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:49:12

Date of Contact	13 AUG 2020
Time of Contact	16:59
Date and Time of Contact (derived)	13 AUG 2020 16:59
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	299 of 2112	

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	303 of 2112	

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	307 of 2112	

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	311 of 2112	

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	315 of 2112	

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	319 of 2112	

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	323 of 2112	

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	327 of 2112	

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	331 of 2112	

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Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Nausea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Vomiting	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Diarrhea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Sore Throat	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	335 of 2112	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Nausea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Vomiting	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Diarrhea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Sore Throat	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>

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Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	339 of 2112	

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
<hr/>		
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
<hr/>		
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
<hr/>		
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
<hr/>		
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
<hr/>		
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
<hr/>		

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	343 of 2112	

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Nausea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Vomiting	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Diarrhea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Sore Throat	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	347 of 2112	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Nausea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Vomiting	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Diarrhea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Sore Throat	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	351 of 2112	

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Form: Symptom Log (14)

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	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Nausea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Vomiting	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Diarrhea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Sore Throat	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	355 of 2112	

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Nausea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Vomiting	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Diarrhea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Sore Throat	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	359 of 2112	

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
<hr/>		
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
<hr/>		
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
<hr/>		
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
<hr/>		
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
<hr/>		
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
<hr/>		

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Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	363 of 2112	

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Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Nausea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Vomiting	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Diarrhea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Sore Throat	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>

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Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	367 of 2112	

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Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Nausea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Vomiting	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Diarrhea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Sore Throat	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>

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Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	371 of 2112	

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Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Nausea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Vomiting	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Diarrhea	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>
Sore Throat	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input checked="" type="radio"/>

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:49:12

Date of Visit	13 AUG 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	13 AUG 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

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:

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

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 _____

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:49:12

[Generate Next COVID-19 Assessment](#)

Yes ☐
No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:49:12

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	15 AUG 2020
Day 5	Yes	17 AUG 2020
Day 7	Yes	19 AUG 2020
Day 9	Yes	21 AUG 2020
Day 14	Yes	26 AUG 2020
Day 21	Yes	02 SEP 2020
Day 28	No	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:50 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 16:50
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	165.0 lb
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

US3252075

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:49:12

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 AUG 2020

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

Was this visit performed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

Visit date (dd MMM yyyy)	
--------------------------	--

Was visit performed at the participant's home or at the clinic?	Home <input type="checkbox"/>
	Clinic <input type="checkbox"/>

Folder OID	SICKD28
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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

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

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

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.

US3252075

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:49:12

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3252075

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:49:12

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

AEID	USA-US108-2020-MRNA-1273-P30 1000001
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	13 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

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

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

SAW PATIENT TODAY AND
PATIENT IS SYMPTOMATIC
WILL START A BABY ASPIRIN
81 MG QD, ZPAK TAKE AS
DIRECTED, CLARITIN 10 MG QD
AND TYLENOL 325MG Q4 QD
FEVER AND PAIN. PATIENT
WITH ELEVATED BLOOD
PRESSURE X2, WITH NO
DIAGNOSIS OF HYPERTENSION.
I RECOMMEND A LOW SALT
DIET AND MONITORING OF
BLOOD PRESSURE AND TO
FOLLOW UP WITH PMD.

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)	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:49:12

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

Yes ☒

No ☐

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

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

Name of Medication	BABY ASPIRIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	COVID POSITIVE
Dose per administration	81
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 AUG 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

Name of Medication	ZPACK
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	COVID POSITIVE
Dose per administration	250
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	13 AUG 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 13 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="radio"/>
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="radio"/>

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

Name of Medication	CLARITIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	COVID POSITIVE
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	13 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)	19 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	803 <input type="checkbox"/>
	804 <input checked="" type="radio"/>	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	COVID POSITIVE
Dose per administration	325
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	13 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)	15 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	803 <input type="checkbox"/>
	804 <input checked="" type="radio"/>	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

Name of Medication	ZPACK
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	COVID POSITIVE
Dose per administration	250
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input checked="" type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)	14 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		19 AUG 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	803 <input type="checkbox"/>
	804 <input checked="" type="radio"/>	

US3252075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:49:12

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3252075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:49:12

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
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US3252075

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:49:12

Date of dosing discontinuation (dd MMM yyyy)

13 AUG 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☒

Other ☐

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

US3252075

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:49:12

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 ☐

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

SAEID	USA-US108-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:49:12

SAEID	USA-US108-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	25/AUG/2020 10:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:49:12

SAEID	USA-US108-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/SEP/2020 09:40
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

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:49:12

SAEID	USA-US108-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	04/NOV/2020 15:59
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

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:49:12

SAEID	USA-US108-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/NOV/2020 17:46
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

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 10:49:12

SAEID	USA-US108-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/NOV/2020 18:24
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

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 10:49:12

SAEID	USA-US108-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/NOV/2020 08:57
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

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 10:49:12

SAEID	USA-US108-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	24/NOV/2020 10:37
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.	<input checked="" type="checkbox"/> True

Audit

US3252075 (Prod: Centex Studies Inc)

US3252075

Form: Participant Creation

Generated On: 26 Nov 2020 10:49:12

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3252075'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	07 Aug 2020 17:29:08

US3252075

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:51:31
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:25

US3252075

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:53:16
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:29:09

US3252075

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:53:16
User entered 'Clinic (Clinic)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:25

US3252075

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	07 Aug 2020 18:40:25

US3252075

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:49:12

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:53:49
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:29:10

US3252075

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:49:12

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:53:53
User entered '67'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:49:12

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:49:12

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '67'	System	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:49:12

Sex

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:53:54
User entered 'Male (M)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:49:12

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:49:12

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered 'I'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:49:12

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered '0'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:49:12

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered '0'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:49:12

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered '0'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:49:12

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered '0'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:49:12

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered '0'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:49:12

If race is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered empty.	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:49:12

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered '0'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:49:12

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered '0'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:49:12

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:21
User entered '7 Aug 2020'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '2020'	System	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:49:12

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:22
User entered 'Amendment 1 (1)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:24
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:49:12

If No, indicate reason for screen fail

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:25
User entered empty.	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:49:12

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:27
User entered empty.	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:49:12

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:49:12

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 17:29:09

US3252075

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:49:12

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Aug 2020 18:41:02

US3252075

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:56
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:02

US3252075

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:49:12

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:04
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:38:30

US3252075

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:49:12

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:32:45
	(b) (4), (b) (6)	21 Oct 2020 17:55:52
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'PER PATIENT NO MEDICATION TAKEN FOR TYPE 2 DIABETES .' (Site from DM).	Joanna Gurrola (b) (4)	26 Sep 2020 01:54:06
	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 14:04:43
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	08 Aug 2020 17:39:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Aug 2020 17:39:49
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 17:39:12
User entered 'TYPE 2 DIABETES'	Shannon Moyer (b) (4)	08 Aug 2020 17:39:02
	(b) (4)	

US3252075

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered 'UN UNK 2019'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:39:02

US3252075

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:49:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered '0'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:39:02

US3252075

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:49:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:39:02

US3252075

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:39:02

US3252075

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:49:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered '0'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:39:02

US3252075

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	08 Aug 2020 17:39:02

US3252075

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '2019'	System	08 Aug 2020 17:39:02

US3252075

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 17:39:02

US3252075

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 17:39:02

US3252075

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:49:12

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:33:00
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:56:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:56:37
Data point term sent to Coder	System	21 Oct 2020 17:55:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'PATIENT COULD NOT RECALL IF HE HAD ANY DIAGNOSIS ASSOCIATED WITH RIGHT HIP REPLACEMENT . ' (Site from DM).	Joanna Gurrola (b) (4) (b) (4)	26 Sep 2020 01:53:00
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 14:05:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Aug 2020 20:51:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Aug 2020 20:51:38
Data point term sent to Coder	System	23 Aug 2020 20:51:02
User entered 'Right Hip Replacement'	Joanna Gurrola (b) (4) (b) (4)	23 Aug 2020 20:50:17

US3252075

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered 'UN Jan 2016'	Joanna Gurrola (b) (4) (b) (4)	23 Aug 2020 20:50:17

US3252075

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:49:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	23 Aug 2020 20:50:17

US3252075

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:49:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	23 Aug 2020 20:50:17

US3252075

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered 'UN Jan 2016'	Joanna Gurrola (b) (4) (b) (4)	23 Aug 2020 20:50:17

US3252075

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:49:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	23 Aug 2020 20:50:17

US3252075

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	23 Aug 2020 20:50:17

US3252075

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '2016'	System	23 Aug 2020 20:50:17

US3252075

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	23 Aug 2020 20:50:17

US3252075

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '2016'	System	23 Aug 2020 20:50:17

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:37
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:39
User entered '07 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:41
User entered '12:20'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:20'	System	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:45
User entered '65' in	Shannon Moyer (b) (4)	08 Aug 2020 17:40:10
DataPoint set to visible.	(b) (4) System	07 Aug 2020 18:41:02

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:50
User entered '165.8' lb	Shannon Moyer (b) (4)	08 Aug 2020 17:40:10
DataPoint set to visible.	(b) (4) System	07 Aug 2020 18:41:02

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '27.64825'	System	16 Sep 2020 23:47:38
User entered '27.6'	System	08 Aug 2020 17:40:10
DataPoint set to visible.	System	07 Aug 2020 18:41:02

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	08 Aug 2020 17:40:10
DataPoint set to visible.	System	07 Aug 2020 18:41:02

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	23 Aug 2020 20:51:54
User entered '98.7' F	(b) (4) Shannon Moyer (b) (4)	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:55
User entered empty; reason for change Data Entry Error	Joanna Gurrola (b) (4)	23 Aug 2020 20:51:54
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:55
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	23 Aug 2020 20:51:54
User entered '80'	Shannon Moyer (b) (4)	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	23 Aug 2020 20:51:54
User entered '16'	(b) (4) Shannon Moyer (b) (4)	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	23 Aug 2020 20:51:54
User entered '145'	(b) (4) Shannon Moyer (b) (4)	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	23 Aug 2020 20:51:54
User entered '90'	(b) (4) Shannon Moyer (b) (4)	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:03:24
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:40:25

US3252075

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:03:24
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	23 Sep 2020 17:04:19
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		14 Sep 2020 02:27:41
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	27 Aug 2020 12:50:48
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		17 Aug 2020 16:46:49
User entered '07 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:40:25

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

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)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:03:51
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

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)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

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)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

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)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

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)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

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)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

No Risk Identified

Audit	User	Time (GMT)
User entered 'I'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered '0'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

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)	21 Oct 2020 18:08:06
User entered '0'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

[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)	21 Oct 2020 18:08:06
User entered '0'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

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)	21 Oct 2020 18:08:06
User entered '0'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered '0'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:49:12

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:16
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:17

US3252075

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:16
User entered '7 Aug 2020'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:17

US3252075

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:16
User entered 'Clinic (Clinic)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:17

US3252075

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	07 Aug 2020 18:41:17

US3252075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:26
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:59:10

US3252075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:49:12

What was the participant's randomization number?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:35
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:54:48
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:54:48
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 17:59:10
User entered '185139' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:59:10

US3252075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:38
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:59:10

US3252075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:49:12

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)	21 Oct 2020 18:08:48
User entered 'No (N)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:34

US3252075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:49:12

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)	21 Oct 2020 18:08:48
User entered 'No (N)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:34

US3252075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:48
User entered 'No (N)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:34

US3252075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:49:12

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:48
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:34

US3252075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:49:12

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:48
User entered 'No (N)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:34

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:49:12

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	23 Aug 2020 20:52:51
User entered '65' in	(b) (4)	
	Shannon Moyer (b) (4)	08 Aug 2020 17:42:18
	(b) (4)	

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:49:12

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	23 Aug 2020 20:52:51
User entered '165.1' lb	(b) (4) Shannon Moyer (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:49:12

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	23 Aug 2020 20:52:51
User entered '65' in	(b) (4) Shannon Moyer (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:49:12

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	23 Aug 2020 20:52:51
User entered '165.1' lb	(b) (4) Shannon Moyer (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:20
User entered '07 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:22
User entered '12:20'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:20'	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:25
User entered '98.1' F	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:26
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:30
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:32
User entered '80'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:34
User entered '16'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:36
User entered '145'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:38
User entered '90'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:49:12

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	23 Aug 2020 20:52:51
User entered '65' in	(b) (4) Shannon Moyer (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:49:12

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	23 Aug 2020 20:52:51
User entered '165.1' lb	(b) (4) Shannon Moyer (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 20:43:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 20:43:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:43:55
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 17:42:18
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 20:43:55
User entered empty.	Shannon Moyer (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 02:54:43
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per Source, correct as is' (Site from System).	Shannon Moyer (b) (4)	20 Aug 2020 20:44:08
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		20 Aug 2020 20:43:55
User entered '14:27' reason for change: Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 20:43:55
User entered empty.	Shannon Moyer (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '07 Aug 2020 14:27'	System	20 Aug 2020 20:43:55
User entered empty.	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F reason for change: Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 20:43:55
User entered empty.	Shannon Moyer (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 20:43:55
User entered empty.	Shannon Moyer (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '81' reason for change: Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 20:43:55
User entered empty.	Shannon Moyer (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 20:43:55
User entered empty.	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '16' reason for change: Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 20:43:55
User entered empty.	Shannon Moyer (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 20:43:55
User entered empty.	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '146' reason for change: Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 20:43:55
User entered empty.	Shannon Moyer (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:43:55
User entered empty.	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '83' reason for change: Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 20:43:55
User entered empty.	Shannon Moyer (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:43:55
User entered empty.	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:09:06
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	23 Aug 2020 20:47:58
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	08 Aug 2020 17:42:30

US3252075

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:09:08
User entered empty; reason for change Data Entry Error	Joanna Gurrola (b) (4)	23 Aug 2020 20:47:58
User entered '07 Aug 2020'	Shannon Moyer (b) (4)	08 Aug 2020 17:42:30

US3252075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:09:31
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:42:05

US3252075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

If No, reason not given

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:09:34
User entered empty.	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:42:05

US3252075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

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)	21 Oct 2020 18:10:03
User entered empty.	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:42:05

US3252075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 18:42:05

US3252075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 20:44:52
User closed query ' Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:47:28
Query ' Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' answered with 'Date format updated.' (Site from DM).	Joanna Gurrola (b) (4)	06 Nov 2020 22:01:43
DataPoint Un-verified.	(b) (4)	06 Nov 2020 22:01:34
User entered '07 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	06 Nov 2020 22:01:34
User opened query ' Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:10:11
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:06
User entered '7 Aug 2020'	Xavier Morales (b) (4)	07 Aug 2020 18:42:05

US3252075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
Query 'Per CDM: Please note this field is not required, unless start time is within 24 hours of dosing time (07-AUG-2020; 13:37hrs)?. Please review and amend accordingly. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:42:53
User opened query 'Per CDM: Please note this field is not required, unless start time is within 24 hours of dosing time (07-AUG-2020; 13:37hrs)?. Please review and amend accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:41:50
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:09
User entered '13:37'	Xavier Morales (b) (4)	07 Aug 2020 18:42:05
	(b) (4)	

US3252075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '07 Aug 2020 13:37'	System	06 Nov 2020 22:01:34
User entered '7 Aug 2020 13:37'	System	07 Aug 2020 18:42:05

US3252075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:17
User entered 'Left Arm (LEFT ARM)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:42:05

US3252075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:21
User entered 'ONCE'	System	07 Aug 2020 18:42:05

US3252075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 18:42:05

US3252075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:49:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:31
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:07

US3252075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:49:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:31
User entered '07 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:07

US3252075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:49:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:31
User entered '12:58'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:07

US3252075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:58'	System	08 Aug 2020 17:43:07

US3252075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:49:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:11:06
User entered '07 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:29

US3252075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:49:12

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:29

US3252075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:49:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:11:06
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:29

US3252075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:49:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:11:06
User entered '12:54'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:29

US3252075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:54'	System	08 Aug 2020 17:43:29

US3252075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:49:12

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:29

US3252075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:49:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:11:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:29

US3252075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:49:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:11:06
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:29

US3252075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 17:43:29

US3252075

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Is the participant continuing to the next visit? (V2 Day 29) = No however, Visit 2 eCRF forms have been completed? Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:47:42
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 20:46:58
User closed query "'Is the participant continuing to the next visit?' is not complete in source, and thus, unable to be verified. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 20:45:38
Query 'Per CDM: Is the participant continuing to the next visit? (V2 Day 29) = No however, Visit 2 eCRF forms have been completed? Please review and update accordingly.' answered with 'Updated and captured in source' (Site from DM).	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 14:32:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 14:32:23
User opened query 'Per CDM: Is the participant continuing to the next visit? (V2 Day 29) = No however, Visit 2 eCRF forms have been completed? Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:55:59
Query "'Is the participant continuing to the next visit?' is not complete in source, and thus, unable to be verified. Please review and reconcile.' answered with 'Reviewed and reconciled as "no".' (Site from CRA).	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 20:39:32
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 20:39:04
User opened query "'Is the participant continuing to the next visit?' is not complete in source, and thus, unable to be verified. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 18:12:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:36

US3252075

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 14:32:23
User entered empty.	System	21 Oct 2020 20:39:04
User entered '1'	System	08 Aug 2020 17:43:36

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:41:45', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '488271d7-2196-49a4-aa3d-81019e9f40c0'	System	07 Aug 2020 19:42:15
User entered 'Yes (Y)'	System	07 Aug 2020 19:42:15

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:41:59', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '488271d7-2196-49a4-aa3d-81019e9f40c0'	System	07 Aug 2020 19:42:15
User entered '98.3'	System	07 Aug 2020 19:42:15

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:06', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '488271d7-2196-49a4-aa3d-81019e9f40c0'	System	07 Aug 2020 19:42:15
User entered 'No (N)'	System	07 Aug 2020 19:42:15

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:12', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '488271d7-2196-49a4-aa3d-81019e9f40c0'	System	07 Aug 2020 19:42:15
User entered '07 Aug 2020 14:42'	System	07 Aug 2020 19:42:15

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 13:57'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 16:27'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:22:46', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a3151d1e-52ae-4056-800a-e32f6644c61d'	System	07 Aug 2020 22:23:35
User entered 'Yes (Y)'	System	07 Aug 2020 22:23:35

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:22:57', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a3151d1e-52ae-4056-800a-e32f6644c61d'	System	07 Aug 2020 22:23:35
User entered '97.5'	System	07 Aug 2020 22:23:35

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:23:03', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a3151d1e-52ae-4056-800a-e32f6644c61d'	System	07 Aug 2020 22:23:35
User entered 'No (N)'	System	07 Aug 2020 22:23:35

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:23:29', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a3151d1e-52ae-4056-800a-e32f6644c61d'	System	07 Aug 2020 22:23:35
User entered '07 Aug 2020 17:23'	System	07 Aug 2020 22:23:35

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 17:22'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 2'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:49:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:36:25', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '07523a48-bb0a-4ab2-bec6-922a38284064'	System	08 Aug 2020 19:36:57
User entered 'Yes (Y)'	System	08 Aug 2020 19:36:57

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:49:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:36:36', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '07523a48-bb0a-4ab2-bec6-922a38284064'	System	08 Aug 2020 19:36:57
User entered '97.9'	System	08 Aug 2020 19:36:57

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:36:43', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '07523a48-bb0a-4ab2-bec6-922a38284064'	System	08 Aug 2020 19:36:57
User entered 'No (N)'	System	08 Aug 2020 19:36:57

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:49:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:36:51', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '07523a48-bb0a-4ab2-bec6-922a38284064'	System	08 Aug 2020 19:36:57
User entered '08 Aug 2020 14:36'	System	08 Aug 2020 19:36:57

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 3'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:49:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:03:22', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'ee55d411-951e-4117-a15d-ff7bccada20c'	System	09 Aug 2020 17:03:53
User entered 'Yes (Y)'	System	09 Aug 2020 17:03:53

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:49:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:03:37', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'ee55d411-951e-4117-a15d-ff7bccada20c'	System	09 Aug 2020 17:03:53
User entered '98.1'	System	09 Aug 2020 17:03:53

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:03:42', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'ee55d411-951e-4117-a15d-ff7bccada20c'	System	09 Aug 2020 17:03:53
User entered 'No (N)'	System	09 Aug 2020 17:03:53

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:49:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:03:50', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'ee55d411-951e-4117-a15d-ff7bccada20c'	System	09 Aug 2020 17:03:53
User entered '09 Aug 2020 12:03'	System	09 Aug 2020 17:03:53

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 4'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:49:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:01:50', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a3d24317-0b5e-432f-bc59-f456231cc823'	System	10 Aug 2020 18:02:20
User entered 'Yes (Y)'	System	10 Aug 2020 18:02:20

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:49:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:02:07', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a3d24317-0b5e-432f-bc59-f456231cc823'	System	10 Aug 2020 18:02:20
User entered '98.6'	System	10 Aug 2020 18:02:20

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:02:11', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a3d24317-0b5e-432f-bc59-f456231cc823'	System	10 Aug 2020 18:02:20
User entered 'No (N)'	System	10 Aug 2020 18:02:20

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:49:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:02:17', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a3d24317-0b5e-432f-bc59-f456231cc823'	System	10 Aug 2020 18:02:20
User entered '10 Aug 2020 13:02'	System	10 Aug 2020 18:02:20

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 5'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:49:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:29:44', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '0c5b78e1-b257-410e-8207-5c40cf3cf64f'	System	11 Aug 2020 18:30:06
User entered 'Yes (Y)'	System	11 Aug 2020 18:30:06

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:49:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:29:52', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '0c5b78e1-b257-410e-8207-5c40cf3cf64f'	System	11 Aug 2020 18:30:06
User entered '97.6'	System	11 Aug 2020 18:30:06

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:29:56', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '0c5b78e1-b257-410e-8207-5c40cf3cf64f'	System	11 Aug 2020 18:30:06
User entered 'No (N)'	System	11 Aug 2020 18:30:06

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:49:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:30:04', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '0c5b78e1-b257-410e-8207-5c40cf3cf64f'	System	11 Aug 2020 18:30:06
User entered '11 Aug 2020 13:30'	System	11 Aug 2020 18:30:06

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 6'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:49:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:31:16', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '722ab52f-7393-4153-94d9-99db0c87ed3e'	System	12 Aug 2020 18:31:42
User entered 'Yes (Y)'	System	12 Aug 2020 18:31:42

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:49:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:31:25', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '722ab52f-7393-4153-94d9-99db0c87ed3e'	System	12 Aug 2020 18:31:42
User entered '97.6'	System	12 Aug 2020 18:31:42

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:31:29', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '722ab52f-7393-4153-94d9-99db0c87ed3e'	System	12 Aug 2020 18:31:42
User entered 'No (N)'	System	12 Aug 2020 18:31:42

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:49:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:31:39', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '722ab52f-7393-4153-94d9-99db0c87ed3e'	System	12 Aug 2020 18:31:42
User entered '12 Aug 2020 13:31'	System	12 Aug 2020 18:31:42

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 7'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:49:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:00:30', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '588670f7-c7f3-4f63-a8fc-b3071109d4f4'	System	13 Aug 2020 17:00:57
User entered 'Yes (Y)'	System	13 Aug 2020 17:00:57

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:49:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:00:36', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '588670f7-c7f3-4f63-a8fc-b3071109d4f4'	System	13 Aug 2020 17:00:57
User entered '97.7'	System	13 Aug 2020 17:00:57

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:00:43', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '588670f7-c7f3-4f63-a8fc-b3071109d4f4'	System	13 Aug 2020 17:00:57
User entered 'No (N)'	System	13 Aug 2020 17:00:57

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:49:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:00:54', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '588670f7-c7f3-4f63-a8fc-b3071109d4f4'	System	13 Aug 2020 17:00:57
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 17:00:57

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-07T14:40:59', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '62a97744-8cf0-4ad8-b389-889f29b4a87b'	System	07 Aug 2020 19:41:26
User entered 'None (1)'	System	07 Aug 2020 19:41:26

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:41:04', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '62a97744-8cf0-4ad8-b389-889f29b4a87b'	System	07 Aug 2020 19:41:26
User entered 'No (N)'	System	07 Aug 2020 19:41:26

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:41:08', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '62a97744-8cf0-4ad8-b389-889f29b4a87b'	System	07 Aug 2020 19:41:26
User entered 'No (N)'	System	07 Aug 2020 19:41:26

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-07T14:41:13', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '62a97744-8cf0-4ad8-b389-889f29b4a87b'	System	07 Aug 2020 19:41:26
User entered 'None (1)'	System	07 Aug 2020 19:41:26

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:41:21', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '62a97744-8cf0-4ad8-b389-889f29b4a87b'	System	07 Aug 2020 19:41:26
User entered '07 Aug 2020 14:41'	System	07 Aug 2020 19:41:26

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 13:57'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 16:27'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-07T17:23:55', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '1db8ea7b-03b2-462d-9960-56a1c053b32c'	System	07 Aug 2020 22:24:40
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 22:24:40

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:24:01', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '1db8ea7b-03b2-462d-9960-56a1c053b32c'	System	07 Aug 2020 22:24:40
User entered 'No (N)'	System	07 Aug 2020 22:24:40

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:24:06', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '1db8ea7b-03b2-462d-9960-56a1c053b32c'	System	07 Aug 2020 22:24:40
User entered 'No (N)'	System	07 Aug 2020 22:24:40

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-07T17:24:21', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '1db8ea7b-03b2-462d-9960-56a1c053b32c'	System	07 Aug 2020 22:24:40
User entered 'None (1)'	System	07 Aug 2020 22:24:40

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:24:36', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '1db8ea7b-03b2-462d-9960-56a1c053b32c'	System	07 Aug 2020 22:24:40
User entered '07 Aug 2020 17:24'	System	07 Aug 2020 22:24:40

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 17:22'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 2'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-08T14:37:01', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '73294901-c9c7-4203-b875-0fc8705e1eff'	System	08 Aug 2020 19:37:42
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 19:37:42

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:49:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:37:09', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '73294901-c9c7-4203-b875-0fc8705e1eff'	System	08 Aug 2020 19:37:42
User entered 'No (N)'	System	08 Aug 2020 19:37:42

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:37:14', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '73294901-c9c7-4203-b875-0fc8705e1eff'	System	08 Aug 2020 19:37:42
User entered 'No (N)'	System	08 Aug 2020 19:37:42

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-08T14:37:26', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '73294901-c9c7-4203-b875-0fc8705e1eff'	System	08 Aug 2020 19:37:42
User entered 'None (1)'	System	08 Aug 2020 19:37:42

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:49:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:37:39', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '73294901-c9c7-4203-b875-0fc8705e1eff'	System	08 Aug 2020 19:37:42
User entered '08 Aug 2020 14:37'	System	08 Aug 2020 19:37:42

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 3'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-09T12:04:02', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '2857ba1c-4531-4edf-bc2f-b64824b6a2c7'	System	09 Aug 2020 17:04:27
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 17:04:27

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:49:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:07', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '2857ba1c-4531-4edf-bc2f-b64824b6a2c7'	System	09 Aug 2020 17:04:27
User entered 'No (N)'	System	09 Aug 2020 17:04:27

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:10', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '2857ba1c-4531-4edf-bc2f-b64824b6a2c7'	System	09 Aug 2020 17:04:27
User entered 'No (N)'	System	09 Aug 2020 17:04:27

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-09T12:04:17', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '2857ba1c-4531-4edf-bc2f-b64824b6a2c7'	System	09 Aug 2020 17:04:27
User entered 'None (1)'	System	09 Aug 2020 17:04:27

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:49:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:25', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '2857ba1c-4531-4edf-bc2f-b64824b6a2c7'	System	09 Aug 2020 17:04:27
User entered '09 Aug 2020 12:04'	System	09 Aug 2020 17:04:27

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 4'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-10T13:02:27', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c307f2d4-a8bc-4c91-b2e6-9b6a583bafd5'	System	10 Aug 2020 18:02:54
User entered 'Does not interfere with activity (2)'	System	10 Aug 2020 18:02:54

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:49:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:02:33', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c307f2d4-a8bc-4c91-b2e6-9b6a583bafd5'	System	10 Aug 2020 18:02:54
User entered 'No (N)'	System	10 Aug 2020 18:02:54

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:02:40', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c307f2d4-a8bc-4c91-b2e6-9b6a583bafd5'	System	10 Aug 2020 18:02:54
User entered 'No (N)'	System	10 Aug 2020 18:02:54

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-10T13:02:46', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c307f2d4-a8bc-4c91-b2e6-9b6a583bafd5'	System	10 Aug 2020 18:02:54
User entered 'None (1)'	System	10 Aug 2020 18:02:54

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:49:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:02:52', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c307f2d4-a8bc-4c91-b2e6-9b6a583bafd5'	System	10 Aug 2020 18:02:54
User entered '10 Aug 2020 13:02'	System	10 Aug 2020 18:02:54

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 5'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-11T13:30:19', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '77f9a3a0-36d8-4ef8-9ec8-f695e1433403'	System	11 Aug 2020 18:30:47
User entered 'None (1)'	System	11 Aug 2020 18:30:47

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:49:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:30:25', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '77f9a3a0-36d8-4ef8-9ec8-f695e1433403'	System	11 Aug 2020 18:30:47
User entered 'No (N)'	System	11 Aug 2020 18:30:47

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:30:30', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '77f9a3a0-36d8-4ef8-9ec8-f695e1433403'	System	11 Aug 2020 18:30:47
User entered 'No (N)'	System	11 Aug 2020 18:30:47

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-11T13:30:37', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '77f9a3a0-36d8-4ef8-9ec8-f695e1433403'	System	11 Aug 2020 18:30:47
User entered 'None (1)'	System	11 Aug 2020 18:30:47

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:49:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:30:45', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '77f9a3a0-36d8-4ef8-9ec8-f695e1433403'	System	11 Aug 2020 18:30:47
User entered '11 Aug 2020 13:30'	System	11 Aug 2020 18:30:47

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 6'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-12T13:31:49', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '42a25494-6fc6-431e-a49b-3188f4a0a795'	System	12 Aug 2020 18:32:21
User entered 'None (1)'	System	12 Aug 2020 18:32:21

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:49:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:31:58', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '42a25494-6fc6-431e-a49b-3188f4a0a795'	System	12 Aug 2020 18:32:21
User entered 'No (N)'	System	12 Aug 2020 18:32:21

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:32:02', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '42a25494-6fc6-431e-a49b-3188f4a0a795'	System	12 Aug 2020 18:32:21
User entered 'No (N)'	System	12 Aug 2020 18:32:21

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-12T13:32:13', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '42a25494-6fc6-431e-a49b-3188f4a0a795'	System	12 Aug 2020 18:32:21
User entered 'None (1)'	System	12 Aug 2020 18:32:21

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:49:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:32:19', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '42a25494-6fc6-431e-a49b-3188f4a0a795'	System	12 Aug 2020 18:32:21
User entered '12 Aug 2020 13:32'	System	12 Aug 2020 18:32:21

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 7'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-13T12:01:02', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '211af047-89d5-4b42-94b9-135c2e135155'	System	13 Aug 2020 17:01:29
User entered 'None (1)'	System	13 Aug 2020 17:01:29

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:49:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:07', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '211af047-89d5-4b42-94b9-135c2e135155'	System	13 Aug 2020 17:01:29
User entered 'No (N)'	System	13 Aug 2020 17:01:29

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:13', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '211af047-89d5-4b42-94b9-135c2e135155'	System	13 Aug 2020 17:01:29
User entered 'No (N)'	System	13 Aug 2020 17:01:29

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-13T12:01:20', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '211af047-89d5-4b42-94b9-135c2e135155'	System	13 Aug 2020 17:01:29
User entered 'None (1)'	System	13 Aug 2020 17:01:29

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:49:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:27', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '211af047-89d5-4b42-94b9-135c2e135155'	System	13 Aug 2020 17:01:29
User entered '13 Aug 2020 12:01'	System	13 Aug 2020 17:01:29

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:19', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cc047361-9314-4c2d-ae2c-2d08044d4968'	System	07 Aug 2020 19:42:44
User entered 'None (0)'	System	07 Aug 2020 19:42:44

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:21', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cc047361-9314-4c2d-ae2c-2d08044d4968'	System	07 Aug 2020 19:42:44
User entered 'None (0)'	System	07 Aug 2020 19:42:44

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:23', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cc047361-9314-4c2d-ae2c-2d08044d4968'	System	07 Aug 2020 19:42:44
User entered 'None (0)'	System	07 Aug 2020 19:42:44

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:26', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cc047361-9314-4c2d-ae2c-2d08044d4968'	System	07 Aug 2020 19:42:44
User entered 'None (0)'	System	07 Aug 2020 19:42:44

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:28', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cc047361-9314-4c2d-ae2c-2d08044d4968'	System	07 Aug 2020 19:42:44
User entered 'None (0)'	System	07 Aug 2020 19:42:44

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:30', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cc047361-9314-4c2d-ae2c-2d08044d4968'	System	07 Aug 2020 19:42:44
User entered 'None (0)'	System	07 Aug 2020 19:42:44

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-07T14:42:33', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cc047361-9314-4c2d-ae2c-2d08044d4968'	System	07 Aug 2020 19:42:44
User entered 'No (N)'	System	07 Aug 2020 19:42:44

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:41', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cc047361-9314-4c2d-ae2c-2d08044d4968'	System	07 Aug 2020 19:42:44
User entered '07 Aug 2020 14:42'	System	07 Aug 2020 19:42:44

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 13:57'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 16:27'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:24:47', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6d8e6d06-b269-41c0-8232-6f41cdce2ac1'	System	07 Aug 2020 22:25:53
User entered 'None (0)'	System	07 Aug 2020 22:25:53

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:24:55', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6d8e6d06-b269-41c0-8232-6f41cdce2ac1'	System	07 Aug 2020 22:25:53
User entered 'None (0)'	System	07 Aug 2020 22:25:53

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:25:04', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6d8e6d06-b269-41c0-8232-6f41cdce2ac1'	System	07 Aug 2020 22:25:53
User entered 'None (0)'	System	07 Aug 2020 22:25:53

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:25:10', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6d8e6d06-b269-41c0-8232-6f41cdce2ac1'	System	07 Aug 2020 22:25:53
User entered 'None (0)'	System	07 Aug 2020 22:25:53

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:25:17', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6d8e6d06-b269-41c0-8232-6f41cdce2ac1'	System	07 Aug 2020 22:25:53
User entered 'None (0)'	System	07 Aug 2020 22:25:53

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:25:27', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6d8e6d06-b269-41c0-8232-6f41cdce2ac1'	System	07 Aug 2020 22:25:53
User entered 'None (0)'	System	07 Aug 2020 22:25:53

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-07T17:25:43', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6d8e6d06-b269-41c0-8232-6f41cdce2ac1'	System	07 Aug 2020 22:25:53
User entered 'No (N)'	System	07 Aug 2020 22:25:53

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:25:50', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6d8e6d06-b269-41c0-8232-6f41cdce2ac1'	System	07 Aug 2020 22:25:53
User entered '07 Aug 2020 17:25'	System	07 Aug 2020 22:25:53

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 17:22'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 2'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:49:12

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:37:47', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6a50bfc8-5572-45cd-8948-c883e2f87665'	System	08 Aug 2020 19:38:31
User entered 'None (0)'	System	08 Aug 2020 19:38:31

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:49:12

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:37:52', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6a50bfc8-5572-45cd-8948-c883e2f87665'	System	08 Aug 2020 19:38:31
User entered 'None (0)'	System	08 Aug 2020 19:38:31

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:49:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:37:57', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6a50bfc8-5572-45cd-8948-c883e2f87665'	System	08 Aug 2020 19:38:31
User entered 'None (0)'	System	08 Aug 2020 19:38:31

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:49:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:38:02', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6a50bfc8-5572-45cd-8948-c883e2f87665'	System	08 Aug 2020 19:38:31
User entered 'None (0)'	System	08 Aug 2020 19:38:31

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:49:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:38:07', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6a50bfc8-5572-45cd-8948-c883e2f87665'	System	08 Aug 2020 19:38:31
User entered 'None (0)'	System	08 Aug 2020 19:38:31

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:49:12

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:38:12', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6a50bfc8-5572-45cd-8948-c883e2f87665'	System	08 Aug 2020 19:38:31
User entered 'None (0)'	System	08 Aug 2020 19:38:31

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-08T14:38:20', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6a50bfc8-5572-45cd-8948-c883e2f87665'	System	08 Aug 2020 19:38:31
User entered 'No (N)'	System	08 Aug 2020 19:38:31

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:49:12

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:38:26', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6a50bfc8-5572-45cd-8948-c883e2f87665'	System	08 Aug 2020 19:38:31
User entered '08 Aug 2020 14:38'	System	08 Aug 2020 19:38:31

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 3'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:49:12

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:31', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c4560b89-03de-4d15-b79a-5943fb7ad4b9'	System	09 Aug 2020 17:05:20
User entered 'None (0)'	System	09 Aug 2020 17:05:20

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:49:12

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:38', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c4560b89-03de-4d15-b79a-5943fb7ad4b9'	System	09 Aug 2020 17:05:20
User entered 'None (0)'	System	09 Aug 2020 17:05:20

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:49:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:45', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c4560b89-03de-4d15-b79a-5943fb7ad4b9'	System	09 Aug 2020 17:05:20
User entered 'None (0)'	System	09 Aug 2020 17:05:20

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:49:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:53', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c4560b89-03de-4d15-b79a-5943fb7ad4b9'	System	09 Aug 2020 17:05:20
User entered 'None (0)'	System	09 Aug 2020 17:05:20

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:49:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:58', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c4560b89-03de-4d15-b79a-5943fb7ad4b9'	System	09 Aug 2020 17:05:20
User entered 'None (0)'	System	09 Aug 2020 17:05:20

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:49:12

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:05:05', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c4560b89-03de-4d15-b79a-5943fb7ad4b9'	System	09 Aug 2020 17:05:20
User entered 'None (0)'	System	09 Aug 2020 17:05:20

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-09T12:05:12', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c4560b89-03de-4d15-b79a-5943fb7ad4b9'	System	09 Aug 2020 17:05:20
User entered 'No (N)'	System	09 Aug 2020 17:05:20

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:49:12

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:05:17', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c4560b89-03de-4d15-b79a-5943fb7ad4b9'	System	09 Aug 2020 17:05:20
User entered '09 Aug 2020 12:05'	System	09 Aug 2020 17:05:20

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 4'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:49:12

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:02:57', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '950bb268-09b6-4cc7-b0bd-4cccb54a543c'	System	10 Aug 2020 18:03:45
User entered 'None (0)'	System	10 Aug 2020 18:03:45

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:49:12

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:03:02', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '950bb268-09b6-4cc7-b0bd-4cccb54a543c'	System	10 Aug 2020 18:03:45
User entered 'None (0)'	System	10 Aug 2020 18:03:45

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:49:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:03:06', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '950bb268-09b6-4cc7-b0bd-4cccb54a543c'	System	10 Aug 2020 18:03:45
User entered 'None (0)'	System	10 Aug 2020 18:03:45

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:49:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:03:11', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '950bb268-09b6-4cc7-b0bd-4cccb54a543c'	System	10 Aug 2020 18:03:45
User entered 'None (0)'	System	10 Aug 2020 18:03:45

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:49:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:03:17', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '950bb268-09b6-4cc7-b0bd-4cccb54a543c'	System	10 Aug 2020 18:03:45
User entered 'None (0)'	System	10 Aug 2020 18:03:45

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:49:12

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:03:24', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '950bb268-09b6-4cc7-b0bd-4cccb54a543c'	System	10 Aug 2020 18:03:45
User entered 'None (0)'	System	10 Aug 2020 18:03:45

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-10T13:03:34', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '950bb268-09b6-4cc7-b0bd-4cccb54a543c'	System	10 Aug 2020 18:03:45
User entered 'No (N)'	System	10 Aug 2020 18:03:45

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:49:12

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:03:43', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '950bb268-09b6-4cc7-b0bd-4cccb54a543c'	System	10 Aug 2020 18:03:45
User entered '10 Aug 2020 13:03'	System	10 Aug 2020 18:03:45

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 5'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:49:12

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:30:51', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '3216189b-0191-496b-a837-db2ed92b7cf7'	System	11 Aug 2020 18:31:41
User entered 'None (0)'	System	11 Aug 2020 18:31:41

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:49:12

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:30:55', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '3216189b-0191-496b-a837-db2ed92b7cf7'	System	11 Aug 2020 18:31:41
User entered 'None (0)'	System	11 Aug 2020 18:31:41

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:49:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:31:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '3216189b-0191-496b-a837-db2ed92b7cf7'	System	11 Aug 2020 18:31:41
User entered 'None (0)'	System	11 Aug 2020 18:31:41

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:49:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:31:08', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '3216189b-0191-496b-a837-db2ed92b7cf7'	System	11 Aug 2020 18:31:41
User entered 'None (0)'	System	11 Aug 2020 18:31:41

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:49:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:31:16', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '3216189b-0191-496b-a837-db2ed92b7cf7'	System	11 Aug 2020 18:31:41
User entered 'None (0)'	System	11 Aug 2020 18:31:41

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:49:12

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:31:24', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '3216189b-0191-496b-a837-db2ed92b7cf7'	System	11 Aug 2020 18:31:41
User entered 'None (0)'	System	11 Aug 2020 18:31:41

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-11T13:31:32', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '3216189b-0191-496b-a837-db2ed92b7cf7'	System	11 Aug 2020 18:31:41
User entered 'No (N)'	System	11 Aug 2020 18:31:41

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:49:12

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:31:38', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '3216189b-0191-496b-a837-db2ed92b7cf7'	System	11 Aug 2020 18:31:41
User entered '11 Aug 2020 13:31'	System	11 Aug 2020 18:31:41

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 6'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:49:12

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:32:25', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '41e2d5f9-ea68-4849-861d-b950314272c0'	System	12 Aug 2020 18:33:12
User entered 'None (0)'	System	12 Aug 2020 18:33:12

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:49:12

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:32:37', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '41e2d5f9-ea68-4849-861d-b950314272c0'	System	12 Aug 2020 18:33:12
User entered 'None (0)'	System	12 Aug 2020 18:33:12

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:49:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:32:41', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '41e2d5f9-ea68-4849-861d-b950314272c0'	System	12 Aug 2020 18:33:12
User entered 'None (0)'	System	12 Aug 2020 18:33:12

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:49:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:32:45', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '41e2d5f9-ea68-4849-861d-b950314272c0'	System	12 Aug 2020 18:33:12
User entered 'None (0)'	System	12 Aug 2020 18:33:12

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:49:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:32:50', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '41e2d5f9-ea68-4849-861d-b950314272c0'	System	12 Aug 2020 18:33:12
User entered 'None (0)'	System	12 Aug 2020 18:33:12

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:49:12

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:32:57', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '41e2d5f9-ea68-4849-861d-b950314272c0'	System	12 Aug 2020 18:33:12
User entered 'None (0)'	System	12 Aug 2020 18:33:12

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-12T13:33:02', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '41e2d5f9-ea68-4849-861d-b950314272c0'	System	12 Aug 2020 18:33:12
User entered 'No (N)'	System	12 Aug 2020 18:33:12

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:49:12

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:33:08', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '41e2d5f9-ea68-4849-861d-b950314272c0'	System	12 Aug 2020 18:33:12
User entered '12 Aug 2020 13:33'	System	12 Aug 2020 18:33:12

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 7'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:49:12

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:36', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c8b3b79e-df6a-488a-b628-31c6547d341d'	System	13 Aug 2020 17:02:35
User entered 'None (0)'	System	13 Aug 2020 17:02:35

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:49:12

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:42', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c8b3b79e-df6a-488a-b628-31c6547d341d'	System	13 Aug 2020 17:02:35
User entered 'None (0)'	System	13 Aug 2020 17:02:35

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:49:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:46', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c8b3b79e-df6a-488a-b628-31c6547d341d'	System	13 Aug 2020 17:02:35
User entered 'None (0)'	System	13 Aug 2020 17:02:35

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:49:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:51', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c8b3b79e-df6a-488a-b628-31c6547d341d'	System	13 Aug 2020 17:02:35
User entered 'None (0)'	System	13 Aug 2020 17:02:35

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:49:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:57', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c8b3b79e-df6a-488a-b628-31c6547d341d'	System	13 Aug 2020 17:02:35
User entered 'None (0)'	System	13 Aug 2020 17:02:35

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:49:12

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:02:13', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c8b3b79e-df6a-488a-b628-31c6547d341d'	System	13 Aug 2020 17:02:35
User entered 'None (0)'	System	13 Aug 2020 17:02:35

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:49:12

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 (b1fbab22f878f305)', Time: '2020-08-13T12:02:22', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c8b3b79e-df6a-488a-b628-31c6547d341d'	System	13 Aug 2020 17:02:35
User entered 'No (N)'	System	13 Aug 2020 17:02:35

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:49:12

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:02:29', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c8b3b79e-df6a-488a-b628-31c6547d341d'	System	13 Aug 2020 17:02:35
User entered '13 Aug 2020 12:02'	System	13 Aug 2020 17:02:35

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:49:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:49:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:16:33
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:25:48

US3252075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:16:33
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:25:48

US3252075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:16:33
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:25:48

US3252075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:16:33
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:25:48

US3252075

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:25:54

US3252075

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 02:25:54

US3252075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:26:37

US3252075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:26:37

US3252075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:26:37

US3252075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:26:37

US3252075

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Nancy Torrence (b) (4)	14 Sep 2020 02:26:48
User entered 'No (N)'	Nancy Torrence (b) (4)	14 Sep 2020 02:26:42

US3252075

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 02:26:48
User entered empty.	System	14 Sep 2020 02:26:42

US3252075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:26:55

US3252075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:26:55

US3252075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:26:55

US3252075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:26:55

US3252075

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:27:00

US3252075

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 02:27:00

US3252075

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:27:41

US3252075

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 15:16:45
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Visit date is correct. Patient was out of window due to being in the illness visit' (Site from System).	Uche Ehiemua (b) (4) (b) (4)	12 Nov 2020 22:30:41
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	06 Nov 2020 22:01:34
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 20:32:20
Amendment Manager: Query text changed to "Visit 2 System Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates."		16 Sep 2020 23:47:38
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Subject visit is within the window.' (Site from System).	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 04:32:26
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	14 Sep 2020 02:27:41
User entered '12 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:27:41

US3252075

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:27:41

US3252075

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	14 Sep 2020 02:27:41

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '13:10'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '12 Sep 2020 13:10'	System	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.8' F	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '89'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '16'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '141'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '81'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:49:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:49:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:34:19

US3252075

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:34:19

US3252075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:32:58

US3252075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

[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).		14 Sep 2020 02:33:07
User entered 'Confirmed COVID-19 (COVID)' reason for change: Data Entry Error	Nancy Torrence (b) (4)	14 Sep 2020 02:33:07
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	14 Sep 2020 02:32:58
	Nancy Torrence (b) (4)	14 Sep 2020 02:32:58
	(b) (4)	

US3252075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:32:58

US3252075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 02:32:58

US3252075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:32:58

US3252075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:32:58

US3252075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 02:32:58

US3252075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:32:58

US3252075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 02:32:58

US3252075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:49:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 02:32:58

US3252075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:49:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:38:37

US3252075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:49:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:38:37

US3252075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:49:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:14'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:38:37

US3252075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '12 Sep 2020 13:14'	System	14 Sep 2020 02:38:37

US3252075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:49:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:35:18

US3252075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:49:12

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:35:18

US3252075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:49:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:35:18

US3252075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:49:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '13:21'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:35:18

US3252075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '12 Sep 2020 13:21'	System	14 Sep 2020 02:35:18

US3252075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:49:12

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:35:18

US3252075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:49:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:35:18

US3252075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:49:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:35:18

US3252075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 02:35:18

US3252075

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:37:47

US3252075

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 02:37:47

US3252075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 02:48:28

US3252075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 02:48:28

US3252075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 02:48:28

US3252075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 02:48:28

US3252075

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 02:48:33

US3252075

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Sep 2020 02:48:33

US3252075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	28 Sep 2020 01:35:09

US3252075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '26 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	28 Sep 2020 01:35:09

US3252075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	28 Sep 2020 01:35:09

US3252075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	28 Sep 2020 01:35:09

US3252075

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	28 Sep 2020 01:35:16

US3252075

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Sep 2020 01:35:16

US3252075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 03:23:54

US3252075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '6 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 03:23:54

US3252075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 03:23:54

US3252075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 03:23:54

US3252075

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 03:23:59

US3252075

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Oct 2020 03:23:59

US3252075

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 14:44:48

US3252075

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	12 Nov 2020 14:44:48

US3252075

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Home (Home)'	(b) (4), (b) (6)	12 Nov 2020 14:44:48

US3252075

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	12 Nov 2020 14:44:48

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '12:57'	(b) (4), (b) (6)	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:57'	System	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	(b) (4), (b) (6)	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73'	(b) (4), (b) (6)	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '15'	(b) (4), (b) (6)	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '132'	(b) (4), (b) (6)	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '75'	(b) (4), (b) (6)	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 14:45:41

US3252075

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 14:45:41

US3252075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:49:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 14:45:59

US3252075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:49:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	12 Nov 2020 14:45:59

US3252075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:49:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:21'	(b) (4), (b) (6)	12 Nov 2020 14:45:59

US3252075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '10 Oct 2020 13:21'	System	12 Nov 2020 14:45:59

US3252075

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 02:43:15

US3252075

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 02:43:15

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 71'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[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 (b1fbab22f878f305)', Time: '2020-10-15T12:49:05', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'f8f3673d-d825-43e4-b36e-4b21082d1a40'	System	15 Oct 2020 17:49:22
User entered 'No (N)'	System	15 Oct 2020 17:49:22

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2020-10-15T12:49:10', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'f8f3673d-d825-43e4-b36e-4b21082d1a40'	System	15 Oct 2020 17:49:22
User entered 'No (N)'	System	15 Oct 2020 17:49:22

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-10-15T12:49:16', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'f8f3673d-d825-43e4-b36e-4b21082d1a40'	System	15 Oct 2020 17:49:22
User entered '15 Oct 2020 12:49:16'	System	15 Oct 2020 17:49:22

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 78'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[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 (b1fbab22f878f305)', Time: '2020-10-21T07:49:04', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b6d5e0d8-3f74-4c84-b6db-f1ab9e8216d8'	System	21 Oct 2020 12:49:30
User entered 'No (N)'	System	21 Oct 2020 12:49:30

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2020-10-21T07:49:15', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b6d5e0d8-3f74-4c84-b6db-f1ab9e8216d8'	System	21 Oct 2020 12:49:30
User entered 'No (N)'	System	21 Oct 2020 12:49:30

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-10-21T07:49:25', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b6d5e0d8-3f74-4c84-b6db-f1ab9e8216d8'	System	21 Oct 2020 12:49:30
User entered '21 Oct 2020 07:49:25'	System	21 Oct 2020 12:49:30

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 99'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[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 (b1fbab22f878f305)', Time: '2020-11-11T07:34:15', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '7769cd69-9f00-447c-80fb-c10888e1a022'	System	11 Nov 2020 13:34:31
User entered 'No (N)'	System	11 Nov 2020 13:34:31

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2020-11-11T07:34:20', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '7769cd69-9f00-447c-80fb-c10888e1a022'	System	11 Nov 2020 13:34:31
User entered 'No (N)'	System	11 Nov 2020 13:34:31

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-11-11T07:34:26', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '7769cd69-9f00-447c-80fb-c10888e1a022'	System	11 Nov 2020 13:34:31
User entered '11 Nov 2020 07:34:26'	System	11 Nov 2020 13:34:31

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Oct 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '08 Oct 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Oct 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 Oct 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Oct 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 Oct 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Oct 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 Oct 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '01 Nov 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '05 Nov 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '08 Nov 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '12 Nov 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[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 (b1fbab22f878f305)', Time: '2020-11-19T18:20:28', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '4e6d37e6-16a9-444e-8fbe-3cf617b38c46'	System	20 Nov 2020 00:20:41
User entered 'No (N)'	System	20 Nov 2020 00:20:41

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2020-11-19T18:20:33', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '4e6d37e6-16a9-444e-8fbe-3cf617b38c46'	System	20 Nov 2020 00:20:41
User entered 'No (N)'	System	20 Nov 2020 00:20:41

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-11-19T18:20:38', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '4e6d37e6-16a9-444e-8fbe-3cf617b38c46'	System	20 Nov 2020 00:20:41
User entered '19 Nov 2020 18:20:38'	System	20 Nov 2020 00:20:41

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[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 (b1fbab22f878f305)', Time: '2020-11-22T19:36:30', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '39b8c22d-872a-4486-b47d-e104e51de338'	System	23 Nov 2020 01:36:41
User entered 'No (N)'	System	23 Nov 2020 01:36:41

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2020-11-22T19:36:35', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '39b8c22d-872a-4486-b47d-e104e51de338'	System	23 Nov 2020 01:36:41
User entered 'No (N)'	System	23 Nov 2020 01:36:41

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-11-22T19:36:39', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '39b8c22d-872a-4486-b47d-e104e51de338'	System	23 Nov 2020 01:36:41
User entered '22 Nov 2020 19:36:39'	System	23 Nov 2020 01:36:41

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:49:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 02:43:38

US3252075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 02:43:38

US3252075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 02:43:38

US3252075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:49:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Patient did not answer phone call, text or email.'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 02:43:38

US3252075

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 02:43:46

US3252075

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:49:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 02:43:46

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:49:12

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:43:01
User entered '13 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	19 Oct 2020 15:13:24
User entered '07 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4)	17 Aug 2020 16:36:35
User entered '13 Aug 2020'	Shannon Moyer (b) (4)	17 Aug 2020 16:29:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:49:12

[Time of Contact](#)

Audit	User	Time (GMT)
User closed query 'In source under Follow Up Safety, date of contact is timed at 16:59. Please review and reconcile. ?' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 22:06:38 29 Oct 2020 22:06:34
Query 'In source under Follow Up Safety, date of contact is timed at 16:59. Please review and reconcile. ?' answered with 'Source reviewed and reconciled.' (Site from CRA).	Joanna Gurrola (b) (4) (b) (4)	28 Oct 2020 14:10:48
User entered '16:59' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	28 Oct 2020 14:10:39
User opened query 'In source under Follow Up Safety, date of contact is timed at 16:59. Please review and reconcile. ?' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Oct 2020 14:43:45
Query 'In source under follow up safety, date of contact is timed at 16:59. Please review and reconcile. ' canceled (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Oct 2020 14:32:58
User opened query 'In source under follow up safety, date of contact is timed at 16:59. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 18:45:06
User entered '00:00'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:29:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:49:12

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 16:59'	System	28 Oct 2020 14:10:39
User entered '13 Aug 2020 00:00'	System	19 Oct 2020 15:13:24
User entered '07 Aug 2020 00:00'	System	17 Aug 2020 16:36:35
User entered '13 Aug 2020 00:00'	System	17 Aug 2020 16:29:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:49:12

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:33:37
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 19:21:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:43:03
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:29:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:49:12

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:43:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	16 Oct 2020 17:20:53
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	24 Aug 2020 21:14:51
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	17 Aug 2020 16:29:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
Query 'Symptom log is not present in source.' canceled (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 15:20:25
User opened query 'Symptom log is not present in source.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:44:31
User entered 'Day 2 (Day 2)'	Joanna Gurrola (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:22
User entered '14 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:23
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:29
User entered '99'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:31
User entered '97.9' F	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:40
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:43
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:46
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:50
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:58
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:02
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:06
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:13
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:28
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:31
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:34
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:38
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:42
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:44
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:46
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:49
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:27:37
User entered '15 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:27:38
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:27:40
User entered '98'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:27:43
User entered '97.8' F	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:27:46
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:27:50
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:27:56
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:28:02
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
User closed query 'Per source, fatigue reported as "none". Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:20:03
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:20:02
Query 'Per source, fatigue reported as "none". Please review and reconcile. ' answered with 'updated' (Site from CRA).	Joanna Gurrola (b) (4)	03 Nov 2020 14:16:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:16:13
User opened query 'Per source, fatigue reported as "none". Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:06:06
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 20:05:23
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:28:07
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:28:12
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:28:16
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:20:38
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 20:06:55
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:28:20
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:20:39
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 20:06:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:28:42
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:20:42
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 20:06:59
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:28:47
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:20:47
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:03
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:28:55
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:20:51
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:05
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:28:59
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:29:03
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:29:07
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:29:09
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:29:12
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
Query 'Symptom log for Day 1 is not present in source. ? ' canceled (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 19:25:58
User opened query 'Symptom log for Day 1 is not present in source. ? ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 15:20:45
User entered 'Day 1 (Day 1)'	Joanna Gurrola (b) (4)	21 Oct 2020 15:23:51
	(b) (4)	

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please confirm initial start date of symptoms and Contact Date are the same (13AUG2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 14:58:10
Query 'Per CDM: Please confirm initial start date of symptoms and Contact Date are the same (13AUG2020) or update accordingly' answered with 'Subject started Symptoms on 13Aug2020 only.' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:17:11
User opened query 'Per CDM: Please confirm initial start date of symptoms and Contact Date are the same (13AUG2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 02:15:29
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:25:52
User entered '13 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47
User entered '13 Oct 2020'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:29:46
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:29:43
User entered '99'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:29:47
User entered '98.7' F	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:29:51
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:29:54
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:29:56
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:29:59
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:02
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:04
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:19
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:23
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:26
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:29
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:35
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:39
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:42
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:44
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:48
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:50
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
Query 'Source is not available in CRIO. ' canceled (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:13:40
User opened query 'Source is not available in CRIO. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 15:47:41
User entered 'Day 4 (Day 4)'	Joanna Gurrola (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:13:45
Query 'Day 4 symptom log source is not updated. ' canceled (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:13:32
User opened query 'Day 4 symptom log source is not updated. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 15:31:37
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 15:31:00
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:29:34
User entered '16 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 16:12:47
User entered '16 Oct 2020'	Joanna Gurrola (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:13:52
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:13:55
User entered '97'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:13:57
User entered '96.9' F	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:13:59
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:09
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:13
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:17
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:19
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:23
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:40
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:45
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:57
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:00
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:03
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:07
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:09
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:12
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:15
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:17
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
Query 'Source is not uploaded in CRIO.' canceled (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:20:09
User opened query 'Source is not uploaded in CRIO.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:00:49
User entered 'Day 5 (Day 5)'	Joanna Gurrola (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:37
User entered '17 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 16:12:47
User entered '17 Oct 2020'	Joanna Gurrola (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:10
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:14
User entered '99'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:16
User entered '98.9' F	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:19
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:28
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:31
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:35
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:37
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:40
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:47
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:49
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:54
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:58
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:04
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:08
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:12
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:18
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:20
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 15:28:49
	(b) (4)	

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:23
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
Query 'Source is not updated in CRIO. ' canceled (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:27:19
User opened query 'Source is not updated in CRIO. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:01:13
User entered 'Day 6 (Day 6)'	Joanna Gurrola (b) (4)	21 Oct 2020 15:45:20
	(b) (4)	

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:27:23
User entered '18 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 16:12:47
User entered '18 Oct 2020'	Joanna Gurrola (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:27:25
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:27:43
User entered '99'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
User closed query 'Per source, temperature is 97.6. Please review and reconcile. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:53:07
	(b) (4), (b) (6)	05 Nov 2020 16:52:56
Query 'Per source, temperature is 97.6. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Joanna Gurrola (b) (4)	03 Nov 2020 14:17:01
User entered '97.6' F reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:16:56
User opened query 'Per source, temperature is 97.6. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:28:06
User entered '99' F	Joanna Gurrola (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:09
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:12
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:15
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:17
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:20
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:22
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:26
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:33
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:36
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:38
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:42
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 15:45:20
	(b) (4)	

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:47
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:49
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:52
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:54
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:55
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
Query 'Source not uploaded to CRIO. ' canceled (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:32:39
User opened query 'Source not uploaded to CRIO. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:01:48
User entered 'Day 7 (Day 7)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:32:44
User entered '19 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:32:47
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:32:54
User entered '97'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:32:56
User entered '98.9' F	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:33:56
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:34:00
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:34:02
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:34:04
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:34:08
User entered 'Moderate (Moderate)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:34:10
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:34:13
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:43
User entered 'Moderate (Moderate)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:46
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:48
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:51
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:55
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:48:00
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:58
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:48:03
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:48:05
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
Query 'Symptom Log is not available in CRIO. Please provide source for review.' canceled (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:50:17
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:15
User opened query 'Symptom Log is not available in CRIO. Please provide source for review.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:25:02
User entered '20 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:18
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:22
User entered '99'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:23
User entered '97.8' F	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:28
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:36
User entered 'Moderate (Moderate)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:40
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:43
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:50
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:56
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:03
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:06
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:09
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:13
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:19
User entered 'Mild (Mild)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:24
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:26
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:29
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:32
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:34
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:28:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:56:53
Query 'Symptom Log is not available in CRIO. Please provide source for review.' canceled (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:28:25
User opened query 'Symptom Log is not available in CRIO. Please provide source for review.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:28:18
User entered '21 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14
User entered '21 Oct 2020'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:56:55
User entered '1' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:45
User entered '0'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:56:58
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:57:00
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
User closed query 'The symptom log is not completed for this date. Please confirm if "not done" or blank should be selected for all symptoms in this log. ? ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:57:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:09
Query 'The symptom log is not completed for this date. Please confirm if "not done" or blank should be selected for all symptoms in this log. ? ' answered with 'this has been updated.' (Site from CRA).	Joanna Gurrola (b) (4)	03 Nov 2020 14:18:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:18:11
User opened query 'The symptom log is not completed for this date. Please confirm if "not done" or blank should be selected for all symptoms in this log. ? ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 22:08:03
Query 'The symptom log is not completed for this date. Please confirm if "not done" should be selected for all symptoms in this log. ' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 22:07:48
User opened query 'The symptom log is not completed for this date. Please confirm if "not done" should be selected for all symptoms in this log. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:57:35
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:15
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:21
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:26
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:29
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:31
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:35
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:38
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:36
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:58:49
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:00:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 19:00:15
User entered '22 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 19:00:15
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 18:42:14
User entered empty.	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:42
User closed query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:01:39
Query 'Please confirm if "assessment not done" should be checked. ' answered with 'this has been updated' (Site from CRA).	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:43
User entered '1' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:25
User opened query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:00:55
User entered '0'	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:01:42
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:01:44
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
User closed query 'The symptom log is not completed for this date. Please confirm if "not done" or blank should be selected for all symptoms in this log.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:01:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:01:46
Query 'The symptom log is not completed for this date. Please confirm if "not done" or blank should be selected for all symptoms in this log.' answered with 'this has been updated. ' (Site from CRA).	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:25
Query 'The symptom log is not completed for this date. Please confirm if "not done" should be selected for all symptoms in this log. ' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 22:08:36
User opened query 'The symptom log is not completed for this date. Please confirm if "not done" or blank should be selected for all symptoms in this log.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 22:08:30
User opened query 'The symptom log is not completed for this date. Please confirm if "not done" should be selected for all symptoms in this log. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:59:05
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:01:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:01:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:01:52
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:25
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:27
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:29
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:31
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:36
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:00:21
User entered '23 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User closed query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:25
	(b) (4), (b) (6)	05 Nov 2020 17:05:22
Query 'Please confirm if "assessment not done" should be checked. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:14
User entered '1' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:02
User opened query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:00:47
User entered '0'	Joanna Gurrola (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:31
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

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

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:33
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
User closed query 'The symptom log is not completed for this date. Please confirm if "not done" should be selected for all symptoms in this log. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:05:36
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:35
Query 'The symptom log is not completed for this date. Please confirm if "not done" should be selected for all symptoms in this log. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:21
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:02
User opened query 'The symptom log is not completed for this date. Please confirm if "not done" should be selected for all symptoms in this log. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:00:31
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:38
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:40
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:41
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:43
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:48
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:52
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:56
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:57
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:59
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:03:14
User entered '24 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User closed query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:42
	(b) (4), (b) (6)	05 Nov 2020 17:06:40
Query 'Please confirm if "assessment not done" should be checked. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:14
User entered '1' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:01
User opened query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:03:35
User entered '0'	Joanna Gurrola (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:44
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:46
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
User closed query 'Symptom log was not completed on this day. Please confirm if the answer can be "not done" or "blank"' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:06:50
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:48
Query 'Symptom log was not completed on this day. Please confirm if the answer can be "not done" or "blank"' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:01
User opened query 'Symptom log was not completed on this day. Please confirm if the answer can be "not done" or "blank"' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:04:08
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:53
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:56
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:04
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:05
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:07
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:09
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:10
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:12
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:14
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:15
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:04:44
User entered '25 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User closed query 'Please review if "assessment not done" should be checked' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:07:59
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:47
Query 'Please review if "assessment not done" should be checked' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola (b) (4)	03 Nov 2020 14:24:33
User entered '1' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:56
User opened query 'Please review if "assessment not done" should be checked' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:05:03
User entered '0'	Joanna Gurrola (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:01
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:19
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:27
User closed query 'As symptom log was not completed, please review if "not done" or "blank" should be completed. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:08:22
Query 'As symptom log was not completed, please review if "not done" or "blank" should be completed. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 14:24:31
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 14:23:56
User opened query 'As symptom log was not completed, please review if "not done" or "blank" should be completed. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:05:55
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:29
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:32
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:36
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:37
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:41
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:47
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:53
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:33
User entered '26 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User closed query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:39
	(b) (4), (b) (6)	05 Nov 2020 17:09:36
Query 'Please confirm if "assessment not done" should be checked. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola (b) (4)	03 Nov 2020 14:25:18
User entered '1' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:25:11
User opened query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:06:49
User entered '0'	Joanna Gurrola (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:41
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:42
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:47
User closed query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:09:44
Query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 14:25:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 14:25:11
User opened query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:07:16
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:50
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:52
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:56
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:57
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:59
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:10:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:10:04
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:10:05
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:10:07
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:10:09
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:10:10
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:10:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:10:15
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:08:00
User entered '27 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:18
User closed query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:11:08
Query 'Please confirm if "assessment not done" should be checked. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola (b) (4)	03 Nov 2020 14:36:45
User entered '1' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:36:36
User opened query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:08:12
User entered '0'	Joanna Gurrola (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:20
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:21
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:23
User closed query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:11:09
Query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 14:36:44
User opened query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:08:23
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:26
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:31
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:35
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:37
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:41
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:48
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:50
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:09:51
User entered '28 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:06
User closed query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:12:59
Query 'Please confirm if "assessment not done" should be checked. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola (b) (4)	03 Nov 2020 15:01:30
User entered '1' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:01:26
User opened query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:10:03
User entered '0'	Joanna Gurrola (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:08
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:10
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:12
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:15
User closed query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:13:13
Query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options.' answered with 'this has been completed.' (Site from CRA).	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 15:01:33
User opened query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:10:13
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:25
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:27
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:29
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:31
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:36
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:38
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:41
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 17 (Day 17)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:39
User entered '29 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User closed query 'Please confirm if "assessment not done" should be checked. ? ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	05 Nov 2020 17:17:04
	(b) (4), (b) (6) (b) (4)	05 Nov 2020 17:16:58
Query 'Please confirm if "assessment not done" should be checked. ? ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 15:25:06
User entered '1' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 15:24:57
User opened query 'Please confirm if "assessment not done" should be checked. ? ' (Site from CRA).	(b) (4), (b) (6) (b) (4)	27 Oct 2020 21:10:54
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:06
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:07
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
User closed query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:19
	(b) (4), (b) (6)	05 Nov 2020 17:17:17
Query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola (b) (4)	03 Nov 2020 15:25:04
User opened query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:10:46
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:15
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:25
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:27
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:31
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:35
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:37
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:38
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:40
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 18 (Day 18)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:11:58
User entered '30 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
User closed query 'Please confirm if "assessment not done" should be checked. ? ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	05 Nov 2020 17:18:07
	(b) (4), (b) (6) (b) (4)	05 Nov 2020 17:18:05
Query 'Please confirm if "assessment not done" should be checked. ? ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 15:26:28
User entered '1' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 15:26:20
User opened query 'Please confirm if "assessment not done" should be checked. ? ' (Site from CRA).	(b) (4), (b) (6) (b) (4)	27 Oct 2020 21:12:10
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:12
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:10
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:17
User closed query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:18:15
Query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 15:26:25
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 15:26:20
User opened query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:12:19
User entered 'None (None)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:21
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:26
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:43
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:41
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:40
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:38
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:36
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:31
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 19 (Day 19)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:14:36
User entered '31 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:00
User closed query 'Please confirm if "assessment not done" should be checked. ? ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:18:57
Query 'Please confirm if "assessment not done" should be checked. ? ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 15:27:31
User entered '1' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 15:27:23
User opened query 'Please confirm if "assessment not done" should be checked. ? ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:14:56
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:02
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:03
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Chills](#)

Audit	User	Time (GMT)
User closed query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 03:51:58
	(b) (4), (b) (6)	05 Nov 2020 17:19:05
Query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola (b) (4)	03 Nov 2020 15:27:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:27:23
User opened query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:14:47
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:25
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:26
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:29
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:31
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:36
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:38
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:41
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:49:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:43
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:49:12

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:46:19
User entered '13 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	19 Oct 2020 19:56:38
User entered '07 Aug 2020'	Shannon Moyer (b) (4)	17 Aug 2020 16:38:19

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:49:12

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:46:37
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:38:19

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:49:12

[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 19:32:37
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 'Done' (Site from System).	Nancy Torrence (b) (4)	17 Sep 2020 19:03:35
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	17 Aug 2020 16:38:19
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	17 Aug 2020 16:38:19

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:49:12

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:46:56
User entered '13 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	19 Oct 2020 19:56:38
User entered '07 Aug 2020'	Shannon Moyer (b) (4)	17 Aug 2020 16:38:19

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:49:12

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:46:58
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:38:19

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:49:12

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:59:37
User entered empty.	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:38:19

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:49:12

[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 14:59:38
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	17 Sep 2020 19:05:19
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	24 Aug 2020 21:15:30
User entered 'No (N)'	Joanna Gurrola (b) (4)	24 Aug 2020 21:15:30
Amendment Manager inserted this DataPoint.	(b) (4) System	21 Aug 2020 02:54:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:49:12

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:59:40
User entered empty.	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:38:19

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:49:12

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:59:41
User entered empty; reason for change Data Entry Error	Nancy Torrence (b) (4)	17 Sep 2020 19:05:19
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	17 Aug 2020 16:38:19

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:49:12

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'I'	System	21 Aug 2020 02:54:48
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:54:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no corresponding AE recorded for this Covid19 Assessment data. Please reconcile and update to record the AE as applicable, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 14:58:43
Query 'Per DM CLR: Please note that there is no corresponding AE recorded for this Covid19 Assessment data. Please reconcile and update to record the AE as applicable, otherwise provide clarification.' answered with 'AE has been reactivated' (Site from DM).	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:30:03
User opened query 'Per DM CLR: Please note that there is no corresponding AE recorded for this Covid19 Assessment data. Please reconcile and update to record the AE as applicable, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:03:46
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:32:55
Query 'Covid-19 Severity Assessment is not noted in source. Please review. ' canceled (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 19:32:49
User opened query 'Covid-19 Severity Assessment is not noted in source. Please review. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 17:21:54
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:33:10
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:33:12
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:33:14
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:33:15
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:33:19
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:53
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:52
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

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)	27 Oct 2020 19:35:50
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:49
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:47
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:45
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:43
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:42
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:40
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:38
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:37
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:35
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:34
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:32
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
User closed query 'Source page (12) is missing, unable to verify. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:27:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:07
Query 'Source page (12) is missing, unable to verify. ' answered with 'this has been uploaded to EMR.' (Site from CRA).	Joanna Gurrola (b) (4)	03 Nov 2020 19:37:04
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	03 Nov 2020 19:36:53
User opened query 'Source page (12) is missing, unable to verify. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 19:59:13
User entered empty.	Joanna Gurrola (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:18
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:20
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:22
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:23
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:25
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:26
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:28
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:29
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:31
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:32
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:34
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:30
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:24
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:22
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:21
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:19
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:17
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:16
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:14
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

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Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:12
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:11
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:09
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:07
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

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[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Joanna Gurrola (b) (4)	24 Nov 2020 16:57:08
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	24 Nov 2020 16:57:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:05
User entered 'Yes (Y)'	Joanna Gurrola (b) (4)	19 Oct 2020 19:57:45
	(b) (4)	

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:04
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:02
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:01
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:28:59
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:28:58
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:49:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:28:56
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:49:12

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:40:51
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Oct 2020 15:21:04
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	24 Aug 2020 16:03:06

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:49:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:49:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:32:34
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:49:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:32:40
User entered '15 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:49:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:49:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:33:15
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:49:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:33:21
User entered '17 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:49:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:49:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:33:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:49:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:33:49
User entered '19 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:49:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:49:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:34:08
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:49:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:34:15
User entered '21 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:49:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:49:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:34:42
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:49:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:34:43
User entered '26 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:49:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:49:12

Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:29:05
DataPoint Un-verified.	Joanna Gurrola (b) (4)	13 Nov 2020 22:54:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	13 Nov 2020 22:54:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:34:28
User closed query 'Please review and consider answering "No" to the question. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 17:34:26
Query 'Please review and consider answering "No" to Shannon Moyer the question. ' answered with 'Updated' (Site from CRA).	(b) (4)	09 Nov 2020 07:21:31
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	09 Nov 2020 07:21:24
User opened query 'Please review and consider answering "No" to the question. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:33:41
User closed query 'Per protocol, saliva sample should have been collected on this date. Please confirm if you can select "not done" for this question' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:33:41
Query 'Per protocol, saliva sample should have been collected on this date. Please confirm if you can select "not done" for this question' answered with 'per query not done is not an option, does NA suffice? ' (Site from CRA).	Shannon Moyer (b) (4)	31 Oct 2020 02:10:06
User opened query 'Per protocol, saliva sample should have been collected on this date. Please confirm if you can select "not done" for this question' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 19:57:44
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 19:57:01
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:35:13
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 19:21:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 19:21:43
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Nancy Torrence (b) (4)	17 Sep 2020 19:21:43
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:49:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:49:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:29:06
DataPoint Un-verified.	Joanna Gurrola (b) (4)	13 Nov 2020 22:54:30
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4)	13 Nov 2020 22:54:30
DataPoint Verified.	Joanna Gurrola (b) (4)	13 Nov 2020 22:54:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:35:14
User entered empty.	(b) (4), (b) (6)	
	Shannon Moyer (b) (4)	02 Sep 2020 15:09:35
	(b) (4)	

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:49:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:49:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Please review and consider answering "No" to the question. ? ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 17:34:34
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:34:33
Query 'Please review and consider answering "No" to the question. ? ' answered with 'Updated' (Site from CRA).	Shannon Moyer (b) (4)	09 Nov 2020 07:21:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 07:21:38
User opened query 'Please review and consider answering "No" to the question. ? ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:34:20
User closed query 'Per protocol, saliva sample should have been collected on this date. Please confirm if you can select "not done" for this question' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:34:20
Query 'Per protocol, saliva sample should have been collected on this date. Please confirm if you can select "not done" for this question' answered with 'per query not done is not an option. please confirm if NA suffices ' (Site from CRA).	Shannon Moyer (b) (4)	31 Oct 2020 02:10:50
User opened query 'Per protocol, saliva sample should have been collected on this date. Please confirm if you can select "not done" for this question' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 19:57:55
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 19:57:49
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:35:17
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 19:21:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 19:21:43
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Nancy Torrence (b) (4)	17 Sep 2020 19:21:43
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 15:09:35
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:49:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:35:19
User entered empty.	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:13:22
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:46:49

US3252075

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:13:23
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:46:49

US3252075

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

[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 15:13:25
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:46:49

US3252075

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	17 Aug 2020 16:46:49

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:13:39
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:13:41
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:13:46
User entered '16:50'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 16:50'	System	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Height (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:13:58
User entered '65' in	Shannon Moyer (b) (4)	17 Aug 2020 16:47:50
DataPoint set to visible.	(b) (4) System	17 Aug 2020 16:46:49

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:14:01
User entered '165.0' lb	Shannon Moyer (b) (4)	17 Aug 2020 16:47:50
DataPoint set to visible.	(b) (4) System	17 Aug 2020 16:46:49

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:14:10
User entered '98.7' F	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:14:17
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:14:21
User entered empty.	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:14:31
User entered '73'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:14:45
User entered '16'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Requery: Please indicate if CS or NCS' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 19:03:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:14:55
Query 'Requery: Please indicate if CS or NCS' answered with 'NCS' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:33:41
User opened query 'Requery: Please indicate if CS or NCS' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 18:22:09
User closed query 'Re-query: Per CDM, below response does not confirm if CS/NCS. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 18:22:09
Query 'Re-query: Per CDM, below response does not confirm if CS/NCS. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Vital signs updated' (Site from DM).	Joanna Gurrola (b) (4)	15 Sep 2020 13:11:40
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 12:34:49
User opened query 'Re-query: Per CDM, below response does not confirm if CS/NCS. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Aug 2020 18:10:40
Un-reviewed for Data Management.	(b) (4), (b) (6)	18 Aug 2020 18:09:26
Reviewed for Data Management.	(b) (4), (b) (6)	18 Aug 2020 18:09:18
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Per PI, Recommendation a low salt diet and monitoring of blood pressure and to follow up with PMD ' (Site from System).	Shannon Moyer (b) (4)	17 Aug 2020 17:07:57
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Aug 2020 16:47:50
User entered '162'	Shannon Moyer (b) (4)	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:15:22
User entered '85'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:15:37
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:50:17

US3252075

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:15:39
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:50:17

US3252075

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:49:12

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:18:16
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:50:35

US3252075

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:49:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:18:17
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:50:35

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:48
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:33:18

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:48
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:33:18

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

[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 15:19:48
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:33:18

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:49:12

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	21 Oct 2020 16:33:18

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:49:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:56
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:33:35

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:49:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:56
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:33:35

US3252075

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:49:12

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:20:00
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:33:41

US3252075

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:49:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:20:00
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 16:33:41

US3252075

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:49:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 20:48:53
User closed query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse events recorded corresponding page. Please review and update accordingly. else clarify' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:33:33
Query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse event recorded corresponding page. Please review and update accordingly. else clarify' answered with 'updated' (Site from DM).	Shannon Moyer (b) (4)	12 Oct 2020 03:07:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	12 Oct 2020 03:07:32
User opened query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse events recorded corresponding page. Please review and update accordingly. else clarify' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 07:57:58
User entered 'No (N)' reason for change: Data Entry Error	Nancy Torrence (b) (4)	28 Sep 2020 01:35:59
User closed query 'PV Query Urgent: Information was provided stating the subject began experiencing symptoms of COVID-19 after receiving the vaccination and a positive COVID-19 was documented. If the subject began experiencing symptoms after receiving the vaccine, please create an adverse event of COVID-19. If the subject was experiencing symptoms prior to vaccination or did not experience any symptoms, please clarify in your response. ' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:42:49
Query 'PV Query Urgent: Information was provided stating the subject began experiencing symptoms of COVID-19 after receiving the vaccination and a positive COVID-19 was documented. If the subject began experiencing symptoms after receiving the vaccine, please create an adverse event of COVID-19. If the subject was experiencing symptoms prior to vaccination or did not experience any symptoms, please clarify in your response. ' answered with 'corrected' (Site from Safety).	Shannon Moyer (b) (4)	24 Aug 2020 17:48:07

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:49:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	24 Aug 2020 17:47:46
User opened query 'PV Query Urgent: Information was provided stating the subject began experiencing symptoms of COVID-19 after receiving the vaccination and a positive COVID-19 was documented. If the subject began experiencing symptoms after receiving the vaccine, please create an adverse event of COVID-19. If the subject was experiencing symptoms prior to vaccination or did not experience any symptoms, please clarify in your response. ' (Site from Safety).	(b) (4), (b) (6)	21 Aug 2020 16:50:07
User entered 'No (N)'	Shannon Moyer (b) (4)	08 Aug 2020 17:43:54

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:46:35
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	(b) (4)	14 Oct 2020 05:15:13
Reviewed for Safety.	Nancy Torrence (b) (4)	25 Aug 2020 14:47:03
User entered	(b) (4), (b) (6)	25 Aug 2020 14:46:52
'USA-US108-2020-mRNA-1273-P301000001'	System	25 Aug 2020 14:46:52
User entered 'New'	(b) (4), (b) (6)	25 Aug 2020 14:46:52

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:29:32
User closed query 'Per CDM: per sponsor review, please consider updating this to COVID-19' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 15:12:08
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)	17 Nov 2020 05:30:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 05:30:52
Query 'Per CDM: per sponsor review, please consider updating this to COVID-19' answered with 'Updated.' (Site from DM).	Joanna Gurrola (b) (4) (b) (4)	17 Nov 2020 05:29:59
Data point term sent to Coder	System	17 Nov 2020 05:29:52
DataPoint Un-verified.	Joanna Gurrola (b) (4) (b) (4)	17 Nov 2020 05:29:42
Coding entries removed.	Joanna Gurrola (b) (4) (b) (4)	17 Nov 2020 05:29:42
User entered 'COVID-19' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	17 Nov 2020 05:29:42
User opened query 'Per CDM: per sponsor review, please consider updating this to COVID-19' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 13:45:21
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:14
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)	09 Nov 2020 07:21:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 07:21:27
Data point term sent to Coder	System	09 Nov 2020 07:20:20
User closed query 'For coding purposes, for AE term COVID 19 POSITIVE, please specify if this is COVID 19 test positive, COVID 19 INFECTION or something else. Please update the term with your response.' (Site from System).	System	09 Nov 2020 07:19:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Adverse event](#)

Audit	User	Time (GMT)
Query 'For coding purposes, for AE term COVID 19 POSITIVE, please specify if this is COVID 19 test positive, COVID 19 INFECTION or something else. Please update the term with your response.' answered with 'Updated' (Site from System). DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:19:34
Coding entries removed.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:19:23
User entered 'COVID-19 infection' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:19:23
User opened query 'For coding purposes, for AE term COVID 19 POSITIVE, please specify if this is COVID 19 test positive, COVID 19 INFECTION or something else. Please update the term with your response.' (Site from System). DataPoint Verified.	Coder Import (b) (4) (b) (4), (b) (6)	07 Nov 2020 18:24:41 05 Nov 2020 17:41:38
User coded data point as SOC: Investigations, HLT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 virus test positive - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 19:28:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 19:28:30
Data point term sent to Coder	System	03 Nov 2020 19:27:54
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
Data point term sent to Coder	System	14 Oct 2020 05:15:30
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
Query 'PV Query: Please provide results of COVID-19 test performed on 13 Aug 2020.' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	25 Sep 2020 12:53:53
Query 'PV Query: Please provide the date the COVID-19 test performed on 07 Aug 2020 resulted.' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	25 Sep 2020 12:53:50
User opened query 'PV Query: Please provide results of COVID-19 test performed on 13 Aug 2020.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Sep 2020 16:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the date the COVID-19 test performed on 07 Aug 2020 resulted.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 16:59:33
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 virus test positive - version MedDRA\23.0.	Coder Import (b) (4)	15 Sep 2020 14:19:46
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	System	15 Sep 2020 14:19:13
Coding entries removed.	Nancy Torrence (b) (4)	15 Sep 2020 14:19:11
	(b) (4)	
User entered 'COVID-19 POSITIVE' reason for change: Data Entry Error	Nancy Torrence (b) (4)	15 Sep 2020 14:19:11
	(b) (4)	
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 virus test positive - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 20:06:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 20:06:43
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 19:08:44
User entered 'COVID Positive'	Shannon Moyer (b) (4)	24 Aug 2020 19:08:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:41:45
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:43:30
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:46:45
User closed query 'PV Query: Please clarify if the subject was symptomatic when they developed Covid-19 or thereafter. If asymptomatic, please delete this baseline asymptomatic case from EDC. If the subject had symptoms, please complete symptom log on COVID assessment pages in EDC.' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 15:59:15
Query 'PV Query: Please clarify if the subject was symptomatic when they developed Covid-19 or thereafter. If asymptomatic, please delete this baseline asymptomatic case from EDC. If the subject had symptoms, please complete symptom log on COVID assessment pages in EDC.' answered with 'this has been updated.' (Site from Safety).	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:29:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:43
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User opened query 'PV Query: Please clarify if the subject was symptomatic when they developed Covid-19 or thereafter. If asymptomatic, please delete this baseline asymptomatic case from EDC. If the subject had symptoms, please complete symptom log on COVID assessment pages in EDC.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 16:58:54
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	24 Aug 2020 21:17:31
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:29:44
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:48:18
User closed query 'Per CDM: Corresponding Con Meds (#1-4) start date is recorded as '13-AUG-2020'? Please review and reconcile Con Med and AE start dates as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:40:46
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 20:50:31
Query 'Per CDM: Corresponding Con Meds (#1-4) start date is recorded as '13-AUG-2020'? Please review and reconcile Con Med and AE start dates as appropriate else clarify.' answered with 'Date has been updated' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:01:58
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 20:00:27
User opened query 'Per CDM: Corresponding Con Meds (#1-4) start date is recorded as '13-AUG-2020'? Please review and reconcile Con Med and AE start dates as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:52:00
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	14 Oct 2020 05:15:13
User closed query 'PV Query: Please confirm if the subject first began exhibiting symptoms of COVID-19 on 13 Aug 2020. If not, please consider updating event start date to onset of symptoms.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 13:39:40
Query 'PV Query: Please confirm if the subject first began exhibiting symptoms of COVID-19 on 13 Aug 2020. If not, please consider updating event start date to onset of symptoms.' answered with 'Done per source' (Site from Safety).	Nancy Torrence (b) (4)	15 Sep 2020 14:19:33
User entered '07 Aug 2020' reason for change: Data Entry Error	Nancy Torrence (b) (4)	15 Sep 2020 14:19:11
User opened query 'PV Query: Please confirm if the subject first began exhibiting symptoms of COVID-19 on 13 Aug 2020. If not, please consider updating event start date to onset of symptoms.' (Site from Safety).	(b) (4), (b) (6)	30 Aug 2020 17:51:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:29:56
User closed query 'Per source, start time is 12:54. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 01:44:36
Query 'Per source, start time is 12:54. Please review and reconcile. ' answered with 'No time on AE. ' (Site from CRA).	Joanna Gurrola (b) (4)	13 Nov 2020 22:51:41
User closed query 'Per CDM: Start time of AE 'COVID-19 POSITIVE' is prior to treatment 1 time (07-AUG-2020; 13:37)? Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:40:50
User opened query 'Per source, start time is 12:54. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 20:52:30
DataPoint Un-verified.	(b) (4), (b) (6)	08 Nov 2020 20:52:08
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 20:51:17
Query 'Per CDM: Start time of AE 'COVID-19 POSITIVE' is prior to treatment 1 time (07-AUG-2020; 13:37)? Please review and update accordingly else clarify.' answered with 'date has been updated' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:03:04
User closed query 'Start time is present for an AE thatSystem did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		06 Nov 2020 20:02:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 20:02:42
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	06 Nov 2020 20:00:27
User opened query 'Per CDM: Start time of AE 'COVID-19 POSITIVE' is prior to treatment 1 time (07-AUG-2020; 13:37)? Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:08:57
Query 'Per CDM: Please note this field is not required, unless start time is within 24 hours of dosing time (07-AUG-2020; 13:37hrs)?. Please review and amend accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:08:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
User opened query 'Per CDM: Please note this field is not required, unless start time is within 24 hours of dosing time (07-AUG-2020; 13:37hrs)?. Please review and amend accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:43:29
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	14 Oct 2020 05:15:13
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Sep 2020 14:19:53
User entered '12:54' reason for change: Data Entry Error	Nancy Torrence (b) (4)	15 Sep 2020 14:19:53
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Sep 2020 14:19:11
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Aug 2020 19:09:09
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	24 Aug 2020 19:09:09
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Aug 2020 19:08:40
User entered '00:00'	Shannon Moyer (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:02:42
User entered '13 Aug 2020 12:54'	System	06 Nov 2020 20:00:27
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '07 Aug 2020 12:54'	System	15 Sep 2020 14:19:53
User entered empty.	System	24 Aug 2020 19:09:09
User entered '13 Aug 2020 00:00'	System	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:38
DataPoint Un-verified.	(b) (4), (b) (6)	08 Nov 2020 20:51:30
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 20:51:24
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	14 Oct 2020 05:15:13
User entered 'No (N)' reason for change: Data Entry Error	Nancy Torrence (b) (4)	15 Sep 2020 14:19:11
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	24 Aug 2020 19:08:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved. The event end date is reported as 20 Aug 2020; however, symptoms were still reported on that day.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 15:36:36
Query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved. The event end date is reported as 20 Aug 2020; however, symptoms were still reported on that day.' answered with 'updated' (Site from Safety).	Shannon Moyer (b) (4)	23 Nov 2020 09:06:09
User opened query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved. The event end date is reported as 20 Aug 2020; however, symptoms were still reported on that day.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 16:40:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:40
User closed query 'PV Query: Please consider updating end date as the subject experienced symptoms on 20Aug2020.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 17:46:16
Query 'PV Query: Please consider updating end date as the subject experienced symptoms on 20Aug2020.' answered with 'updated.' (Site from Safety).	Joanna Gurrola (b) (4)	13 Nov 2020 23:06:14
User entered '20 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	13 Nov 2020 22:51:54
User opened query 'PV Query: Please consider updating end date as the subject experienced symptoms on 20Aug2020.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:38:21
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	14 Oct 2020 05:15:13
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 13:39:45
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'End date entered per source' (Site from Safety).	Nancy Torrence (b) (4)	15 Sep 2020 14:21:08

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Sep 2020 14:20:39
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	15 Sep 2020 14:20:39
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Sep 2020 14:19:11
User entered '19 Aug 2020' reason for change: Data Entry Error	Nancy Torrence (b) (4)	15 Sep 2020 14:19:11
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	26 Aug 2020 11:39:59
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:31:54
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:28:37
User entered empty.	Shannon Moyer (b) (4)	24 Aug 2020 19:08:40

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End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:42
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Nov 2020 20:00:27
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	(b) (4)	14 Oct 2020 05:15:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 16:04:30
Query 'Data is required. Please provide.' answered with 'Time is unknown' (Site from System).	Nancy Torrence (b) (4)	15 Sep 2020 14:21:20
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Sep 2020 14:19:11
User entered empty.	Shannon Moyer (b) (4)	24 Aug 2020 19:08:40

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered empty.	System	24 Aug 2020 19:08:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:03:56
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:03:42
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:46
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:47
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:49
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:52
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:54
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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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)	17 Nov 2020 21:31:56
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:58
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:32:00
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:32:01
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:32:03
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 18:55:48
User closed query 'Per CDM: AE started after First Dose, however Relationship to Investigational Product is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 13:42:50
Query 'Per CDM: AE started after First Dose, however Relationship to Investigational Product is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'UPDATED' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	19 Nov 2020 08:08:54
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	19 Nov 2020 08:08:40
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	19 Nov 2020 08:08:40
User opened query 'Per CDM: AE started after First Dose, however Relationship to Investigational Product is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:42:41
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:35:12
Query 'Per source, "Not related" please review and reconcile. ' canceled (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 21:35:02
User opened query 'Per source, "Not related" please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 21:33:01
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 21:32:31
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:32:25
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:19:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	17 Sep 2020 16:43:58
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	17 Sep 2020 16:43:58
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	17 Sep 2020 16:43:58
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	24 Aug 2020 19:08:40
User entered 'Not Related (NOT RELATED)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:07:58
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered 'Not Related (NOT RELATED)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

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)	07 Nov 2020 21:01:02
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)	07 Nov 2020 21:01:01
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 'Patient tested positive for COVID-19 during SCR/DAY1 visit. Dosing was discontinued and AE was reported.' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 20:52:08
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 'This has been reflected on dosing discontinuation ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:51:28
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	06 Nov 2020 20:51:00
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)	06 Nov 2020 08:16:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:07:29
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	14 Oct 2020 05:15:13

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Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:52:09
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:08:44
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	(b) (4)	14 Oct 2020 05:15:13
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.' canceled (Site from Safety).	Nancy Torrence (b) (4)	25 Sep 2020 12:54:37
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)	23 Sep 2020 16:59:06
User entered 'I'	Shannon Moyer (b) (4)	24 Aug 2020 19:08:40

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Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:08:58
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:36:59
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 18:09:08
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:09:01
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	(b) (4)	14 Oct 2020 05:15:13
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 13:39:59
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Entered' (Site from Safety).	Nancy Torrence (b) (4)	15 Sep 2020 14:21:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Nancy Torrence (b) (4)	15 Sep 2020 14:20:39
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Aug 2020 11:40:31
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:31:48
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:29:43
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 19:10:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 19:10:17

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[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	24 Aug 2020 19:10:17
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 19:08:40
User entered empty.	Shannon Moyer (b) (4)	24 Aug 2020 19:08:40

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:35:21
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Response noted ,SAE Narrative = TYLENOL 325MG Q4 PRN. However, in CM eCRF this was given Once Daily. Please review and reconcile AE and CM eCRF pages as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 21:58:40
Query 'PV Query: The subject's blood pressure was reported as elevated x2. The only reported BP is 162/85 on 13 Aug 2020. Please provide the additional reading.' answered with 'PI meant that the blood pressure of 162/85 was x2, not two separate readings.' (Site from Safety).	Joanna Gurrola (b) (4) (b) (4)	24 Nov 2020 17:00:35
Query 'PV Query: Per COVID-19 Severity Assessment form, the subject displayed evidence of pneumonia. Please describe in the narrative section. If none, please update form accordingly.' answered with 'this has been updated as there is not documentation in EMR about pneumonia.' (Site from Safety).	Joanna Gurrola (b) (4) (b) (4)	24 Nov 2020 16:57:40
Query 'Per CDM: Response noted ,SAE Narrative = TYLENOL 325MG Q4 PRN. However, in CM eCRF this was given Once Daily. Please review and reconcile AE and CM eCRF pages as appropriate.' answered with 'This has updated.' (Site from DM).	Joanna Gurrola (b) (4) (b) (4)	24 Nov 2020 16:55:37
User opened query 'PV Query: The subject's blood pressure was reported as elevated x2. The only reported BP is 162/85 on 13 Aug 2020. Please provide the additional reading.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 16:40:40
User opened query 'PV Query: Per COVID-19 Severity Assessment form, the subject displayed evidence of pneumonia. Please describe in the narrative section. If none, please update form accordingly.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 16:39:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:38:38
User opened query 'Per CDM: Response noted ,SAE Narrative = TYLENOL 325MG Q4 PRN. However, in CM eCRF this was given Once Daily. Please review and reconcile AE and CM eCRF pages as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:23:25

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = TYLENOL 325MG Q4 PRN. However, in CM eCRF this was given Once Daily. Please review and reconcile AE and CM eCRF pages as appropriate.
' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:23:25
Query 'Per DM CLR: SAE Narrative = TYLENOL 325MG Q4 PRN. However, in CM eCRF this was given Once Daily. Please review and reconcile AE and CM eCRF pages as appropriate. ' answered with 'Updated.' (Site from DM).	Joanna Gurrola (b) (4) (b) (4)	17 Nov 2020 05:33:44
User entered 'SAW PATIENT TODAY AND PATIENT IS SYMPTOMATIC WILL START A BABY ASPIRIN 81 MG QD, ZPAK TAKE AS DIRECTED, CLARITIN 10 MG QD AND TYLENOL 325MG Q4 QD FEVER AND PAIN. PATIENT WITH ELEVATED BLOOD PRESSURE X2, WITH NO DIAGNOSIS OF HYPERTENSION. I RECOMMEND A LOW SALT DIET AND MONITORING OF BLOOD PRESSURE AND TO FOLLOW UP WITH PMD.' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	17 Nov 2020 05:33:32
User closed query 'PV Query: Please clarify if the subject was symptomatic when they developed Covid-19 or thereafter. If asymptomatic, please delete this baseline asymptomatic case from EDC. If the subject had symptoms, please complete symptom log on COVID assessment pages in EDC.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 17:46:23
User opened query 'Per DM CLR: SAE Narrative = TYLENOL 325MG Q4 PRN. However, in CM eCRF this was given Once Daily. Please review and reconcile AE and CM eCRF pages as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 11:34:11
Query 'PV Query: Please clarify if the subject was symptomatic when they developed Covid-19 or thereafter. If asymptomatic, please delete this baseline asymptomatic case from EDC. If the subject had symptoms, please complete symptom log on COVID assessment pages in EDC.' answered with 'updated. ' (Site from Safety).	Joanna Gurrola (b) (4) (b) (4)	13 Nov 2020 23:07:50

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Saw patient today and patient is symptomatic will start a baby aspirin 81 mg QD, ZPAK take as directed, Claritin 10 mg QD and Tylenol 325mg Q4 PRN fever and pain. Patient with elevated blood pressure x2, with no diagnosis of hypertension. I recommend a low salt diet and monitoring of blood pressure and to follow up with PMD.' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	13 Nov 2020 23:07:45
User opened query 'PV Query: Please clarify if the subject was symptomatic when they developed Covid-19 or thereafter. If asymptomatic, please delete this baseline asymptomatic case from EDC. If the subject had symptoms, please complete symptom log on COVID assessment pages in EDC.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:37:47
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	14 Oct 2020 05:15:13
Query 'PV Query: Please report medically relevant clinical course following administration of blinded study vaccine and COVID + test result.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 12:54:49
User opened query 'PV Query: Please report medically relevant clinical course following administration of blinded study vaccine and COVID + test result.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 16:59:17
Query 'PV Query: Please clarify if the subject was symptomatic and when they developed symptoms of Covid-19. If the subject was asymptomatic, please confirm in your response.' canceled (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 16:58:38
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)	16 Sep 2020 13:40:19

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please report medically relevant clinical course following administration of blinded study vaccine and COVID + test result.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 13:40:15
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 'Done' (Site from Safety).	Nancy Torrence (b) (4) (b) (4)	15 Sep 2020 14:26:32
Query 'PV Query: Please report medically relevant clinical course following administration of blinded study vaccine and COVID + test result.' answered with 'IP withdrawn per source' (Site from Safety).	Nancy Torrence (b) (4) (b) (4)	15 Sep 2020 14:22:46
User opened query 'PV Query: Please report medically relevant clinical course following administration of blinded study vaccine and COVID + test result.' (Site from Safety).	(b) (4), (b) (6)	30 Aug 2020 17:51:52
User opened query 'PV Query: Please clarify if the subject was symptomatic and when they developed symptoms of Covid-19. If the subject was asymptomatic, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	26 Aug 2020 11:42:02
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)	26 Aug 2020 11:40:17
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.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:31:46

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:31:44
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:30:01
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)	25 Aug 2020 14:27:15
Query 'PV Query Urgent: Information was provided stating the subject began experiencing symptoms of COVID-19 after receiving the vaccination and a positive COVID-19 was documented. If the subject began experiencing symptoms after receiving the vaccine, please create an adverse event of COVID-19 and provide all relevant details. If the subject was experiencing symptoms prior to vaccination or did not experience any symptoms, please clarify in your response.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:26:35

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query Urgent: Information was provided stating the subject began experiencing symptoms of COVID-19 after receiving the vaccination and a positive COVID-19 was documented. If the subject began experiencing symptoms after receiving the vaccine, please create an adverse event of COVID-19 and provide all relevant details. If the subject was experiencing symptoms prior to vaccination or did not experience any symptoms, please clarify in your response.' (Site from Safety). User entered empty.	(b) (4), (b) (6) (b) (4)	25 Aug 2020 14:24:13
	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	System	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered 'I'	System	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:49:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:49:12

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 20:52:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	24 Aug 2020 19:10:39
User entered 'No (N)'	Shannon Moyer (b) (4)	08 Aug 2020 17:44:15

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BABY ASPIRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 21:34:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 21:34:42
Data point term sent to Coder	System	24 Aug 2020 19:22:26
User entered 'Baby Aspirin'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:22
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:25
User entered 'COVID Positive'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:27
User entered '81'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:29
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:31
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:34
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:37
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:41
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:47
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Aug 2020 19:22:38
User entered '13 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4)	24 Aug 2020 19:22:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Aug 2020 19:22:23
User entered '13 Aug ' (non-conformant).	Shannon Moyer (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:50
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per source, end date is 19AUG2020. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 18:11:43
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:11:37
Query 'Per source, end date is 19AUG2020. ' answered with 'updated' (Site from CRA).	Joanna Gurrola (b) (4)	29 Oct 2020 04:46:32
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	29 Oct 2020 04:46:19
User opened query 'Per source, end date is 19AUG2020. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:53:07
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 16:52:51
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:52:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:11:45
User entered '19 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	29 Oct 2020 04:46:19
User entered empty.	Shannon Moyer (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query "The question "was this medication taken for a solicited event?" is not answered in source and thus cannot be verified. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:11:09
	(b) (4), (b) (6)	05 Nov 2020 18:11:07
Query "The question "was this medication taken for a solicited event?" is not answered in source and thus cannot be verified. ' answered with 'updating ' (Site from CRA).	Joanna Gurrola (b) (4)	29 Oct 2020 04:46:47
	(b) (4)	
User opened query "The question "was this medication taken for a solicited event?" is not answered in source and thus cannot be verified. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:53:33
User entered 'No (N)'	Shannon Moyer (b) (4)	24 Aug 2020 19:22:23
	(b) (4)	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:49:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:53:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: Z-PAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 10:22:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 10:22:39
Data point term sent to Coder	System	24 Aug 2020 19:24:31
User entered 'ZPack'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:53:52
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:53:55
User entered 'COVID Positive'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:53:57
User entered '250'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:53:59
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:02
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:06
User entered 'twice daily (BID)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:07
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:10
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:13
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:15
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:17
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	08 Sep 2020 22:26:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:22
User entered '13 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4)	08 Sep 2020 22:26:12
User entered empty.	Shannon Moyer (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query "'Was this medication taken for a solicited event?'" is not answered in source. Please review. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 18:10:59
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:10:31
Query "'Was this medication taken for a solicited event?'" is not answered in source. Please review. ' answered with 'updated source' (Site from CRA).	Joanna Gurrola (b) (4)	29 Oct 2020 04:48:48
User opened query "'Was this medication taken for a solicited event?'" is not answered in source. Please review. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:54:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:26
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:24
User entered 'No (N)'	Shannon Moyer (b) (4)	24 Aug 2020 19:23:41
	(b) (4)	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:49:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review Drug Name Claritan and ensure the correct name has been used as this cannot be referenced. Update name if applicable or provide clarification' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	25 Oct 2020 10:58:44
	(b) (4), (b) (6)	23 Oct 2020 16:56:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: CLARITHROMYCIN, PRODUCTSYNONYM: CLARITIN [CLARITHROMYCIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 23:25:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 23:25:42
	(b) (4)	
Data point term sent to Coder	System	17 Sep 2020 18:55:53
Query 'Per DM CLR: Please review Drug Name Claritan and ensure the correct name has been used as this cannot be referenced. Update name if applicable or provide clarification' answered with 'Corrected spelling' (Site from DM).	Nancy Torrence (b) (4)	17 Sep 2020 18:55:34
	(b) (4)	
Coding entries removed.	Nancy Torrence (b) (4)	17 Sep 2020 18:55:12
	(b) (4)	
User entered 'CLARITiN' reason for change: Data Entry Error	Nancy Torrence (b) (4)	17 Sep 2020 18:55:12
	(b) (4)	
User opened query 'Per DM CLR: Please review Drug Name Claritan and ensure the correct name has been used as this cannot be referenced. Update name if applicable or provide clarification' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 16:01:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: CLARITHROMYCIN, PRODUCTSYNONYM: CLARITIN [CLARITHROMYCIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 08:09:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 08:09:43
	(b) (4)	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	24 Aug 2020 19:24:36
User entered 'Claritan'	Shannon Moyer (b) (4)	24 Aug 2020 19:24:34
	(b) (4)	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:56:51
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:56:53
User entered 'COVID Positive'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 10:58:50
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:56:58
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'has been updated' (Site from DM).	Xavier Morales (b) (4)	22 Sep 2020 14:05:54
User entered '10' reason for change: Data Entry Error	Xavier Morales (b) (4)	22 Sep 2020 14:05:46
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 16:01:58
User entered '1'	Shannon Moyer (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:57:12
User entered 'mg (mg)' reason for change: Data Entry Error	Xavier Morales (b) (4)	22 Sep 2020 14:05:46
User entered 'tablet (TABLET)'	Shannon Moyer (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:57:14
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:57:17
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:57:24
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:57:26
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:57:29
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:57:33
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:57:36
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per source, the stop date is 19AUG2020. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 18:47:09
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:47:07
Query 'Per source, the stop date is 19AUG2020. ' answered with 'updated' (Site from CRA).	Joanna Gurrola (b) (4)	29 Oct 2020 04:49:08
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	29 Oct 2020 04:49:03
User opened query 'Per source, the stop date is 19AUG2020. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 17:00:44
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:47:10
User entered '19 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	29 Oct 2020 04:49:03
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 17:00:48
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:00:46
User entered empty.	Shannon Moyer (b) (4)	24 Aug 2020 19:24:34
	(b) (4)	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query "The question "was this medication taken for a solicited event?" is not answered. Please review and reconcile. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:47:17
	(b) (4), (b) (6)	05 Nov 2020 18:47:12
Query "The question "was this medication taken for a solicited event?" is not answered. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Joanna Gurrola (b) (4)	29 Oct 2020 04:49:12
User opened query "The question "was this medication taken for a solicited event?" is not answered. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 17:01:18
User entered 'No (N)'	Shannon Moyer (b) (4)	24 Aug 2020 19:24:34
	(b) (4)	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:49:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:01:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 02:47:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 02:47:45
Data point term sent to Coder Coding entries removed.	System Nancy Torrence (b) (4)	14 Sep 2020 02:46:50 14 Sep 2020 02:46:30
User entered 'Tylenol' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:46:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 06:31:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 06:31:47
Data point term sent to Coder User entered 'Tylenol'	System Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:26:38 24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:01:29
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:01:32
User entered 'COVID Positive'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:01:34
User entered '325'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:01:35
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:02:32
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:02:35
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:02:41
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:02:44
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:02:46
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:02:48
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:02:50
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:48:12
User closed query 'Per source, the stop date is 15AUG2020. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 18:48:10
Query 'Per source, the stop date is 15AUG2020. ' answered with 'updated' (Site from CRA).	Joanna Gurrola (b) (4)	29 Oct 2020 04:49:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	29 Oct 2020 04:49:25
User opened query 'Per source, the stop date is 15AUG2020. ' (Site from CRA).	Joanna Gurrola (b) (4)	23 Oct 2020 17:03:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 19:25:53
	Shannon Moyer (b) (4)	
	(b) (4)	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:48:14
User entered '15 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	29 Oct 2020 04:49:25
User entered empty.	Shannon Moyer (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query "The question "was this medication taken for a solicited event?" is not answered. Please review and reconcile. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:48:18
	(b) (4), (b) (6)	05 Nov 2020 18:48:16
Query "The question "was this medication taken for a solicited event?" is not answered. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Joanna Gurrola (b) (4)	29 Oct 2020 04:49:34
User opened query "The question "was this medication taken for a solicited event?" is not answered. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 17:03:34
User entered 'No (N)'	Shannon Moyer (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:49:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: Z-PAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:29:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:29:56
Data point term sent to Coder	System	08 Sep 2020 22:28:36
User entered 'ZPack'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:27
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:28
User entered 'COVID Positive'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:30
User entered '250'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:33
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:36
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Joanna Gurrola (b) (4)	24 Nov 2020 16:55:05
	(b) (4)	
User entered 'four times daily (QID)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	24 Nov 2020 16:55:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 16:55:38
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	08 Sep 2020 22:27:42
	(b) (4)	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:40
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:42
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:47
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:49
User entered '14 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:50
User entered '0'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:54
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:56
User entered '19 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query "'Was this medication taken for a solicited event?'" is not answered in source. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 18:48:39
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:48:38
Query "'Was this medication taken for a solicited event?'" is not answered in source. Please review and reconcile. ' answered with 'updated source ' (Site from CRA).	Joanna Gurrola (b) (4)	29 Oct 2020 04:50:28
User opened query "'Was this medication taken for a solicited event?'" is not answered in source. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:56:32
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 16:56:08
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:58
User entered 'No (N)'	Shannon Moyer (b) (4)	08 Sep 2020 22:27:42
	(b) (4)	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 16:55:05
User entered '1'	System	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:49:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:49:12

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	23 Aug 2020 20:48:11
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	08 Aug 2020 17:44:42

US3252075

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:49:12

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	(b) (4), (b) (6)	06 Nov 2020 20:51:00

US3252075

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:49:12

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4), (b) (6)	06 Nov 2020 20:51:00

US3252075

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:49:12

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:51:00

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: Postal Code

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: Postal Code

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:49:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
User entered '25/Aug/2020 10:48'	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:49:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'I'	(b) (4), (b) (6)	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: Postal Code

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:49:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
User entered '16/Sep/2020 09:40'	System	16 Sep 2020 13:40:55

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:49:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:59:43
User entered 'I'	(b) (4), (b) (6)	16 Sep 2020 13:40:55

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: Postal Code

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:49:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
User entered '04/Nov/2020 15:59'	System	04 Nov 2020 15:59:59

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:49:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:46:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
User entered 'I'	(b) (4), (b) (6)	04 Nov 2020 15:59:59

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: Postal Code

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:49:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '16/Nov/2020 17:46'	System	16 Nov 2020 17:46:49

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:49:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 18:24:30
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 17:46:49

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: Postal Code

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 10:49:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '16/Nov/2020 18:24'	System	16 Nov 2020 18:24:46

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 10:49:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Nov 2020 13:56:47
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 18:24:46

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: Postal Code

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 10:49:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '22/Nov/2020 08:57'	System	22 Nov 2020 13:57:02

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 10:49:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
User entered 'I'	(b) (4), (b) (6)	22 Nov 2020 13:57:02

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

Site Address: Postal Code

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered (b) (6)	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:49:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 10:49:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 10:37'	System	24 Nov 2020 15:37:29

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 10:49:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 15:37:29