

US3672097 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3672097

Form: Participant Creation

Generated On: 26 Nov 2020 11:09:54

[Participant ID](#)

US3672097

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

US3672097

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3672097

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:54

Date of Birth (MMM yyyy)	(b) (6) 1981
Age	38
Age Units	YEARS
Age (Derived)	38
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3672097

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:54

Date of Informed Consent (<i>dd MMM yyyy</i>)	13 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

US3672097

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:09:54

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3672097

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:09:54

Were any significant conditions reported?

Yes ☐

No ☒

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	13 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:50 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 12:50
Height (<i>xxx.x</i>)	165.4 cm
Weight (<i>xxx.x</i>)	97.3 kg
BMI (<i>xxx.x</i>)	35.56656 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672097

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:54

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.

US3672097

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:54

Date of assessment (*dd MMM yyyy*) 13 AUG 2020

Is the participant of childbearing potential? Yes ☒ No ☐

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____

Date of last menstruation unknown False

US3672097

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	13 AUG 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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 NO RISK IDENTIFIED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:54

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 103830

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☐

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:54

Height	ND - Not Done
Weight	ND - Not Done

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	12:50 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 12:50
Temperature (xxx.x)	98.6 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	14:11 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 14:11
Temperature (xxx.x)	98.8 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3672097

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:54

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.

US3672097

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed _____ Urine ☐

Serum ☐

Result _____ Positive ☐

Negative ☐

Was FSH sample collected? Yes ☐

No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:54

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) 13 AUG 2020

What was the treatment time? (00:00-23:59) 13:35 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 13:35

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

US3672097

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:54

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

13 AUG 2020

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

13:15 (24 HR)

Collection date and time (derived)

13 AUG 2020 13:15

US3672097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:54

Collection date (<i>dd MMM yyyy</i>)			13 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	12:41	13 AUG 2020 12:41
Nasopharyngeal Swab 2	No		

US3672097

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 14:04

PC Open Date & Time

13 AUG 2020 13:55

PC Close Date & Time

13 AUG 2020 16:25

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

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

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 13 AUG 2020 18:31

PC Open Date & Time 13 AUG 2020 17:20

PC Close Date & Time 14 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 19:26

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:54

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

98.3 °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

15 AUG 2020 14:25

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:54

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

16 AUG 2020 18:33

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:54

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

97.5 °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

17 AUG 2020 18:32

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:54

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 18:51

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	98.3 °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):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	19 AUG 2020 18:32
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 8

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

98.5 °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

20 AUG 2020 18:32

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

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

13 AUG 2020 14:05

PC Open Date & Time

13 AUG 2020 13:55

PC Close Date & Time

13 AUG 2020 16:25

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

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

13 AUG 2020 18:32

PC Open Date & Time

13 AUG 2020 17:20

PC Close Date & Time

14 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:54

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

14 AUG 2020 19:27

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:54

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

15 AUG 2020 14:26

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:54

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

16 AUG 2020 18:34

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:54

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

17 AUG 2020 18:32

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:54

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

18 AUG 2020 18:52

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:54

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

19 AUG 2020 18:32

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 14:06
PC Open Date & Time	13 AUG 2020 13:55
PC Close Date & Time	13 AUG 2020 16:25

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 18:32
PC Open Date & Time	13 AUG 2020 17:20
PC Close Date & Time	14 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:54

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 ☒

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:54

Yes ☐	
PC Time stamp	14 AUG 2020 19:28
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:54

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 ☒

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:54

Yes ☐	
PC Time stamp	15 AUG 2020 14:26
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:54

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 ☒

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:54

Yes ☐	
PC Time stamp	16 AUG 2020 18:35
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:54

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 ☒

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:54

Yes ☐	
PC Time stamp	17 AUG 2020 18:33
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:54

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 ☒

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:54

Yes ☐	
PC Time stamp	18 AUG 2020 18:54
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:54

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 ☒

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:54

Yes ☐	
PC Time stamp	19 AUG 2020 18:33
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 20 AUG 2020 18:32

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp 20 AUG 2020 18:32

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp 21 AUG 2020 18:36

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

22 AUG 2020 18:41

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

23 AUG 2020 18:55

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	20 AUG 2020 18:32
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	21 AUG 2020 18:36
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	22 AUG 2020 18:41
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 11

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

No ☒

Yes ☐

PC Time stamp

23 AUG 2020 18:55

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3672097

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672097

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672097

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672097

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672097

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672097

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672097

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

Was this visit performed?	Yes ☐
	No ☒

Visit date (dd MMM yyyy)	

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

Folder OID	VISIT2

US3672097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:54

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.

US3672097

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

Was the pregnancy test performed?	Yes ☐
	No ☐
Date of test (<i>dd MMM yyyy</i>)	
Test performed	Urine ☐
	Serum ☐
Result	Positive ☐
	Negative ☐
Was FSH sample collected?	Yes ☐
	No ☐
Collection date	
Collection time	
Collection date and time (derived)	

US3672097

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:54

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? _____

US3672097

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:54

Was the sample collected?	Yes ☐
	No ☐

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3672097

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:54

Collection date (<i>dd MMM yyyy</i>)			
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

US3672097

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672097

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

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

ON ILLNESS TRACK

If Contact Not Made, please provide Comments

US3672097

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672097

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

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

ON ILLNESS TRACK

If Contact Not Made, please provide Comments

US3672097

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672097

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

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

ON ILLNESS TRACK

If Contact Not Made, please provide Comments

US3672097

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672097

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	13 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:10 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 13:10
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672097

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:54

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.

US3672097

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:54

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	13 OCT 2020
Collection time (<i>00:00-23:59</i>)	13:35 (24 HR)
Collection date and time (derived)	13 OCT 2020 13:35

US3672097

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 OCT 2020 14:36:13

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 NOV 2020 19:53:09

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2020 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2020 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2020 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2020 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2020 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2020 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 131

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 145

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

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13 JAN 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 187

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 215

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 JAN 2022 00:01

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26 JAN 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 MAR 2022 00:01

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16 MAR 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 MAR 2022 00:01

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30 MAR 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

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02 APR 2022 00:01

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06 APR 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

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13 APR 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

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20 APR 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 APR 2022 00:01

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27 APR 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

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04 MAY 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

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11 MAY 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 MAY 2022 00:01

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01 JUN 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 JUN 2022 00:01

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08 JUN 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

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15 JUN 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

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18 JUN 2022 00:01

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22 JUN 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 JUN 2022 00:01

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29 JUN 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

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02 JUL 2022 00:01

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06 JUL 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

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09 JUL 2022 00:01

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13 JUL 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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20 JUL 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

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06 AUG 2022 00:01

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10 AUG 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

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17 AUG 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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20 AUG 2022 00:01

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24 AUG 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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31 AUG 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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07 SEP 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3672097

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672097

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672097

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:54

Date of Contact	11 SEP 2020
Time of Contact	12:30
Date and Time of Contact (derived)	11 SEP 2020 12:30
Type of Contact	Clinic Visit - Scheduled ☒
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	312 of 2035	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	12 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	316 of 2035	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	320 of 2035	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	14 SEP 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	324 of 2035	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	328 of 2035	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	332 of 2035	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	17 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	336 of 2035	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	340 of 2035	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	19 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.0 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	344 of 2035	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.0 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	348 of 2035	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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

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

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

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

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

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	21 SEP 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.0 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	352 of 2035	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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

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

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

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

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

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	22 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	95.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	356 of 2035	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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

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

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

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

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

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	23 SEP 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	360 of 2035	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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

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

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

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

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

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	24 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	364 of 2035	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:54

Date of Visit	11 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Date of Test	11 SEP 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	1

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

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:

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

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 _____

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:09:54

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 11:09:54

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	13 SEP 2020
Day 5	Yes	15 SEP 2020
Day 7	Yes	17 SEP 2020
Day 9	Yes	19 SEP 2020
Day 14	Yes	24 SEP 2020
Day 21	Yes	1 OCT 2020
Day 28	Yes	13 OCT 2020

US3672097

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:40 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:40
Height (<i>xxx.x</i>)	165.4 cm
Weight (<i>xxx.x</i>)	95.4 kg
Temperature (<i>xxx.x</i>)	98.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672097

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3672097

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:09:54

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

11 SEP 2020

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD28

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 13:10
Height (xxx.x)	163.8 cm
Weight (xxx.x)	97.6 kg
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3672097

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:09:54

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 OCT 2020

US3672097

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:09:54

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

AEID	USA-US116-2020-MRNA-1273-P30 1000002
Adverse event	COVID-19
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☒ No ☐
Start date (dd MMM yyyy)	7 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	13 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	382 of 2035

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

PATIENT CAME IN FOR D29
VISIT BUT REPORTED
SYMPTOMS BEGINNING 9/7/20
SO WAS CHANGED TO AN
ILLNESS DAY 1 VISIT. PT ONLY
EVER TREATED WITH MIDOL
FOR SYMPTOMS BUT DID
ADDITIONALLY EXPERIENCE
HEADACHE WHICH SHE TOOK
MOTRIN FOR AS WELL.
ANOTHER COVID-19 SWAB
TEST WAS DONE ON 01 OCT
2020, IN WHICH THE SUBJECT
TESTED POSITIVE AGAIN.

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)	

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☒ No ☐
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	19 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	20 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

385 of 2035

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☐ Related ☒ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☒ No ☐
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	19 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	23 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	387 of 2035

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☐ Related ☒ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:09:54

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

Yes ☒

No ☐

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

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ☒ No ☐
Indication	CHRONIC DISEASE PROPHYLAXIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☒ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

Name of Medication	PROBIOTIC
Prophylaxis	Yes ☒ No ☐
Indication	CHRONIC DISEASE PROPHYLAXIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☒ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

Name of Medication	MOTRIN
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHE
Dose per administration	200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	16 AUG 2020	
Was this medication taken for solicited event?	Yes ☒	No ☐
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

Name of Medication	MOTRIN
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHE
Dose per administration	200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

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

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

Name of Medication	MIDOL
Prophylaxis	Yes ☐ No ☒
Indication	COVID
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☒ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		07 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	COVID-19
Dose per administration	600
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		13 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		13 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	COVID-19
Dose per administration	600
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3672097

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:09:54

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3672097

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:09:54

Date of dosing discontinuation (dd MMM yyyy)

11 SEP 2020

Primary reason for dosing discontinuation

AE (specify) ☒

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

AE#1

US3672097

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:09:54

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 ☐

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

SAEID	USA-US116-2020-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	1156 BOWMAN ROAD
Site Address: City	MOUNT PLEASANT
Site Address: State	
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:09:54

SAEID	USA-US116-2020-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	1156 BOWMAN ROAD
Site Address: City	MOUNT PLEASANT
Site Address: State	
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/SEP/2020 14:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:09:54

SAEID	USA-US116-2020-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	1156 BOWMAN ROAD
Site Address: City	MOUNT PLEASANT
Site Address: State	
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/OCT/2020 16:25
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

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:09:54

SAEID	USA-US116-2020-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	1156 BOWMAN ROAD
Site Address: City	MOUNT PLEASANT
Site Address: State	
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/OCT/2020 17:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:09:54

SAEID	USA-US116-2020-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	1156 BOWMAN ROAD
Site Address: City	MOUNT PLEASANT
Site Address: State	
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	03/NOV/2020 23:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3672097 (Prod: Coastal Carolina Research Center)

US3672097

Form: Participant Creation

Generated On: 26 Nov 2020 11:09:54

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:28:32
User entered 'US3672097'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:49:26

US3672097

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:18:32
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:34:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 17:54:07

US3672097

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:18:34
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:34:07
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:49:27

US3672097

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:18:35
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:34:07
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Aug 2020 17:54:07

US3672097

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	13 Aug 2020 17:54:07

US3672097

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered (b) (6) 1981'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 16:49:28

US3672097

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:54

[Age](#)

Audit	User	Time (GMT)
User entered '38'	(b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:54

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:54

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '38'	System	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:54

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:54

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:54

White

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:54

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:54

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:54

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:54

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:54

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:54

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:54

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:54

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '2020'	System	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:54

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:54

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:54

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:54

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 16:49:27

US3672097

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:54

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:54:49

US3672097

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 17:54:49

US3672097

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:09:54

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 06:51:38
Query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' answered with 'confirm' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 17:53:40
User opened query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 12:02:28
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:29:35

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '12:50'	(b) (4), (b) (6)	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:50'	System	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '165.4' cm	(b) (4), (b) (6)	14 Aug 2020 15:30:11
DataPoint set to visible.	System	13 Aug 2020 17:54:49

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '97.3' kg	(b) (4), (b) (6)	14 Aug 2020 15:30:11
DataPoint set to visible.	System	13 Aug 2020 17:54:49

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '35.56656'	System	16 Sep 2020 23:55:32
User entered '35.6'	System	14 Aug 2020 15:30:11
DataPoint set to visible.	System	13 Aug 2020 17:54:49

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	14 Aug 2020 15:30:11
DataPoint set to visible.	System	13 Aug 2020 17:54:49

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:27:11
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:31:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 20:31:01
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 17:03:02
User entered '98.6' F	(b) (4), (b) (6)	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please consider to keep the Route of measurement field as “Blank”, since Temperature is recorded as ND and please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:55:19
Query 'Per CDM: Please consider to keep the Route of measurement field as “Blank”, since Temperature is recorded as ND and please update accordingly. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:23:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 15:23:45
User opened query 'Per CDM: Please consider to keep the Route of measurement field as “Blank”, since Temperature is recorded as ND and please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:28:37
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 20:31:01
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[If Other, specify](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please consider to keep "If other, specify" as Blank since Temperature is recorded as ND. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 06:09:33
Query 'Per CDM: Please consider to keep "If other, specify" as Blank since Temperature is recorded as ND. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 12:28:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 12:28:25
User opened query 'Per CDM: Please consider to keep "If other, specify" as Blank since Temperature is recorded as ND. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:55:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 20:31:01
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:30:20

US3672097

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 15:30:20

US3672097

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 15:30:38

US3672097

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:54

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:30:46
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:30:38

US3672097

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:54

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	14 Aug 2020 15:30:46
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	14 Aug 2020 15:30:38
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:30:38

US3672097

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:54

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:30:38

US3672097

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:54

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:30:38

US3672097

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:54

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 15:30:38

US3672097

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:54

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:30:38

US3672097

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:54

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 15:30:38

US3672097

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:30:56

US3672097

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 15:30:56

US3672097

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	14 Aug 2020 15:30:56

US3672097

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	14 Aug 2020 15:30:56

US3672097

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: As per the CCG Guidelines Page number 24, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 03:52:41
Query 'Per CDM: As per the CCG Guidelines Page number 24, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 21:05:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:05:44
User opened query 'Per CDM: As per the CCG Guidelines Page number 24, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 06:11:49
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:30:56

US3672097

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:30:56

US3672097

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:30:56

US3672097

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 15:30:56

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

[Specify](#)

Audit	User	Time (GMT)
User entered 'no risk identified'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

[Other](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:54

[Specify](#)

Audit	User	Time (GMT)
User entered 'resident in a community with person to person transmisson'	(b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 17:54:18

US3672097

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 17:54:18

US3672097

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Aug 2020 17:54:18

US3672097

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	13 Aug 2020 17:54:18

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	13 Aug 2020 17:14:25

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:54

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:13:17
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:13:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 17:14:25
User entered '103830' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 17:14:25

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 17:14:25

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 17:54:29

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 17:54:29

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 17:54:29

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:54

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 17:54:29

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:54

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 17:54:29

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
Query 'Per CDM: This field requires a Yes or No response. Please complete.' canceled (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 19:56:34
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:30:52
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:51
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:03:38

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:54

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Re-query: Response provided as 'reconciled' However, data has not been updated yet. Please consider to keep 'UNIT' (kg) blank for 'WEIGHT' data field. thank you' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 04:10:35
Query 'Per CDM: Re-query: Response provided as 'reconciled' However, data has not been updated yet. Please consider to keep 'UNIT' (kg) blank for 'WEIGHT' data field. thank you' answered with 'weight unit reconciled' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:50:37
User opened query 'Per CDM: Re-query: Response provided as 'reconciled' However, data has not been updated yet. Please consider to keep 'UNIT' (kg) blank for 'WEIGHT' data field. thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:37:07
User closed query 'Per CDM: Re-query: Response provided as 'updated per query' However, Please consider to keep unit blank for Weight data field. thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:37:07
Query 'Per CDM: Re-query: Response provided as 'updated per query' However, Please consider to keep unit blank for Weight data field. thank you. ' answered with 'reconciled ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:05:41
User opened query 'Per CDM: Re-query: Response provided as 'updated per query' However, Please consider to keep unit blank for Weight data field. thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 19:43:36
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 19:43:36
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated per query' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:28:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 19:28:08
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Aug 2020 04:30:37

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:54

Height

Audit	User	Time (GMT)
User entered '165.4' cm	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:54

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 16:50:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 19:28:08
User entered '97.3' kg	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:54

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Re-query: Response provided as 'reconciled' However, data has not been updated yet. Please consider to keep 'UNIT' (kg) blank for 'WEIGHT' data field. thank you' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 04:10:35
Query 'Per CDM: Re-query: Response provided as 'reconciled' However, data has not been updated yet. Please consider to keep 'UNIT' (kg) blank for 'WEIGHT' data field. thank you' answered with 'weight unit reconciled' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:50:37
User opened query 'Per CDM: Re-query: Response provided as 'reconciled' However, data has not been updated yet. Please consider to keep 'UNIT' (kg) blank for 'WEIGHT' data field. thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:37:07
User closed query 'Per CDM: Re-query: Response provided as 'updated per query' However, Please consider to keep unit blank for Weight data field. thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:37:07
Query 'Per CDM: Re-query: Response provided as 'updated per query' However, Please consider to keep unit blank for Weight data field. thank you. ' answered with 'reconciled ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:05:41
User opened query 'Per CDM: Re-query: Response provided as 'updated per query' However, Please consider to keep unit blank for Weight data field. thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 19:43:36
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 19:43:36
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated per query' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:28:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 19:28:08
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Aug 2020 04:30:37

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:54

Height

Audit	User	Time (GMT)
User entered '165.4' cm	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:54

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 16:50:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 19:28:08
User entered '97.3' kg	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 15:32:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 15:32:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:32:42
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 15:32:13
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:32:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '12:50' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:32:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:50'	System	14 Aug 2020 15:32:42
User entered empty.	System	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:32:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:32:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:32:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 15:32:42
User entered empty.	System	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:32:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 15:32:42
User entered empty.	System	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '113' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:32:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 15:32:42
User entered empty.	System	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '74' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:32:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 15:32:42
User entered empty.	System	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:54

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Re-query: Response provided as 'reconciled' However, data has not been updated yet. Please consider to keep 'UNIT' (kg) blank for 'WEIGHT' data field. thank you' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 04:10:35
Query 'Per CDM: Re-query: Response provided as 'reconciled' However, data has not been updated yet. Please consider to keep 'UNIT' (kg) blank for 'WEIGHT' data field. thank you' answered with 'weight unit reconciled' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:50:37
User opened query 'Per CDM: Re-query: Response provided as 'reconciled' However, data has not been updated yet. Please consider to keep 'UNIT' (kg) blank for 'WEIGHT' data field. thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:37:07
User closed query 'Per CDM: Re-query: Response provided as 'updated per query' However, Please consider to keep unit blank for Weight data field. thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:37:07
Query 'Per CDM: Re-query: Response provided as 'updated per query' However, Please consider to keep unit blank for Weight data field. thank you. ' answered with 'reconciled ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:05:41
User opened query 'Per CDM: Re-query: Response provided as 'updated per query' However, Please consider to keep unit blank for Weight data field. thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 19:43:36
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 19:43:36
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated per query' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:28:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 19:28:08
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Aug 2020 04:30:37

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:54

Height

Audit	User	Time (GMT)
User entered '165.4' cm	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:54

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 16:50:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 19:28:08
User entered '97.3' kg	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 15:33:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 15:33:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:33:19
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 15:32:13
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:33:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 09:11:55
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'time is correct as entered ' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 15:33:29
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).		14 Aug 2020 15:33:19
User entered '14:11' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:33:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 14:11'	System	14 Aug 2020 15:33:19
User entered empty.	System	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:33:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:33:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:33:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 15:33:19
User entered empty.	System	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:33:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 15:33:19
User entered empty.	System	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '109' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:33:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 15:33:19
User entered empty.	System	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '76' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 15:33:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 15:33:19
User entered empty.	System	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:33:36

US3672097

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 15:33:36

US3672097

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 07:22:17
Query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.'	(b) (4), (b) (6)	28 Sep 2020 21:06:06
answered with 'updated' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:06:02
User opened query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 12:39:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:33:44

US3672097

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:06:02
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 15:33:44

US3672097

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

[Test performed](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:06:02
User entered 'Urine (URINE)'	(b) (4), (b) (6)	14 Aug 2020 15:33:44

US3672097

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

[Result](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:06:02
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	14 Aug 2020 15:33:44

US3672097

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: As per the CCG Guidelines Page number 24, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 07:22:15
Query 'Per CDM: As per the CCG Guidelines Page number 24, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 21:06:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:06:02
User opened query 'Per CDM: As per the CCG Guidelines Page number 24, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 12:40:15
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:33:44

US3672097

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:33:44

US3672097

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:33:44

US3672097

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 15:33:44

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:54

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '13:35'	(b) (4), (b) (6)	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 13:35'	System	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:34:03

US3672097

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 15:34:03

US3672097

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:15'	(b) (4), (b) (6)	14 Aug 2020 15:34:03

US3672097

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 13:15'	System	14 Aug 2020 15:34:03

US3672097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 15:34:16

US3672097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:54

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Aug 2020 15:34:16

US3672097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:34:16

US3672097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:41'	(b) (4), (b) (6)	14 Aug 2020 15:34:16

US3672097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:41'	System	14 Aug 2020 15:34:16

US3672097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:54

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Aug 2020 15:34:16

US3672097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:34:16

US3672097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:34:16

US3672097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 15:34:16

US3672097

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

[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? is 'YES' however, there is no further visits recorded, please review and confirm with a response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 06:09:08
Query 'Per CDM: Is the participant continuing to the next visit? is 'YES' however, there is no further visits recorded, please review and confirm with a response. Thank you.' answered with 'there are' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:08:09
User opened query 'Per CDM: Is the participant continuing to the next visit? is 'YES' however, there is no further visits recorded, please review and confirm with a response. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:59:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:34:20

US3672097

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 15:34:20

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T14:04:41', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'c795f14d-c646-43a3-80ad-c4d93e894196'	System	13 Aug 2020 18:05:00
User entered 'Yes (Y)'	System	13 Aug 2020 18:05:00

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T14:04:49', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'c795f14d-c646-43a3-80ad-c4d93e894196'	System	13 Aug 2020 18:05:00
User entered '98.8'	System	13 Aug 2020 18:05:00

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T14:04:53', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'c795f14d-c646-43a3-80ad-c4d93e894196'	System	13 Aug 2020 18:05:00
User entered 'No (N)'	System	13 Aug 2020 18:05:00

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T14:04:58', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'c795f14d-c646-43a3-80ad-c4d93e894196'	System	13 Aug 2020 18:05:00
User entered '13 Aug 2020 14:04'	System	13 Aug 2020 18:05:00

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 13:55'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 16:25'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T18:31:02', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'd14d9ea7-37a3-4d76-b06a-51b119b7c838'	System	13 Aug 2020 22:31:16
User entered 'Yes (Y)'	System	13 Aug 2020 22:31:16

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T18:31:06', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'd14d9ea7-37a3-4d76-b06a-51b119b7c838'	System	13 Aug 2020 22:31:16
User entered '98.3'	System	13 Aug 2020 22:31:16

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T18:31:09', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'd14d9ea7-37a3-4d76-b06a-51b119b7c838'	System	13 Aug 2020 22:31:16
User entered 'No (N)'	System	13 Aug 2020 22:31:16

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T18:31:13', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'd14d9ea7-37a3-4d76-b06a-51b119b7c838'	System	13 Aug 2020 22:31:16
User entered '13 Aug 2020 18:31'	System	13 Aug 2020 22:31:16

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 17:20'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 2'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-14T19:26:41', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '11354065-67e5-4362-ab46-775689ca81c6'	System	14 Aug 2020 23:26:55
User entered 'Yes (Y)'	System	14 Aug 2020 23:26:55

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-14T19:26:46', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '11354065-67e5-4362-ab46-775689ca81c6'	System	14 Aug 2020 23:26:55
User entered '97.4'	System	14 Aug 2020 23:26:55

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-14T19:26:49', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '11354065-67e5-4362-ab46-775689ca81c6'	System	14 Aug 2020 23:26:55
User entered 'No (N)'	System	14 Aug 2020 23:26:55

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-14T19:26:53', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '11354065-67e5-4362-ab46-775689ca81c6'	System	14 Aug 2020 23:26:55
User entered '14 Aug 2020 19:26'	System	14 Aug 2020 23:26:55

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 3'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-15T14:25:23', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '8846b1e2-ec4c-4451-b921-0c0cc64752b7'	System	15 Aug 2020 18:25:38
User entered 'Yes (Y)'	System	15 Aug 2020 18:25:38

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-15T14:25:27', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '8846b1e2-ec4c-4451-b921-0c0cc64752b7'	System	15 Aug 2020 18:25:38
User entered '98.3'	System	15 Aug 2020 18:25:38

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-15T14:25:29', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '8846b1e2-ec4c-4451-b921-0c0cc64752b7'	System	15 Aug 2020 18:25:38
User entered 'No (N)'	System	15 Aug 2020 18:25:38

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-15T14:25:33', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '8846b1e2-ec4c-4451-b921-0c0cc64752b7'	System	15 Aug 2020 18:25:38
User entered '15 Aug 2020 14:25'	System	15 Aug 2020 18:25:38

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 4'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-16T18:33:21', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '9fb919b8-c40c-4e58-8ba8-72ca0dc28be3'	System	16 Aug 2020 22:33:57
User entered 'Yes (Y)'	System	16 Aug 2020 22:33:57

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-16T18:33:26', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '9fb919b8-c40c-4e58-8ba8-72ca0dc28be3'	System	16 Aug 2020 22:33:57
User entered '98.6'	System	16 Aug 2020 22:33:57

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-16T18:33:45', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '9fb919b8-c40c-4e58-8ba8-72ca0dc28be3'	System	16 Aug 2020 22:33:57
User entered 'Yes (Y)'	System	16 Aug 2020 22:33:57

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirm' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 09:11:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Aug 2020 22:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-16T18:33:49', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '9fb919b8-c40c-4e58-8ba8-72ca0dc28be3'	System	16 Aug 2020 22:33:57
User entered '1'	System	16 Aug 2020 22:33:57

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-16T18:33:49', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '9fb919b8-c40c-4e58-8ba8-72ca0dc28be3'	System	16 Aug 2020 22:33:57
User entered '0'	System	16 Aug 2020 22:33:57

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-16T18:33:54', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '9fb919b8-c40c-4e58-8ba8-72ca0dc28be3'	System	16 Aug 2020 22:33:57
User entered '16 Aug 2020 18:33'	System	16 Aug 2020 22:33:57

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 5'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-17T18:32:16', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '352cee08-578f-42a2-8da9-8291ad2f463d'	System	17 Aug 2020 22:32:32
User entered 'Yes (Y)'	System	17 Aug 2020 22:32:32

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-17T18:32:21', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '352cee08-578f-42a2-8da9-8291ad2f463d'	System	17 Aug 2020 22:32:32
User entered '97.5'	System	17 Aug 2020 22:32:32

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-17T18:32:23', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '352cee08-578f-42a2-8da9-8291ad2f463d'	System	17 Aug 2020 22:32:32
User entered 'No (N)'	System	17 Aug 2020 22:32:32

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-17T18:32:26', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '352cee08-578f-42a2-8da9-8291ad2f463d'	System	17 Aug 2020 22:32:32
User entered '17 Aug 2020 18:32'	System	17 Aug 2020 22:32:32

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 6'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-18T18:51:34', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '9c762d2f-bfa3-450f-bcc0-b88d8920d54b'	System	18 Aug 2020 22:51:47
User entered 'Yes (Y)'	System	18 Aug 2020 22:51:47

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-18T18:51:37', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '9c762d2f-bfa3-450f-bcc0-b88d8920d54b'	System	18 Aug 2020 22:51:47
User entered '97.2'	System	18 Aug 2020 22:51:47

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-18T18:51:40', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '9c762d2f-bfa3-450f-bcc0-b88d8920d54b'	System	18 Aug 2020 22:51:47
User entered 'No (N)'	System	18 Aug 2020 22:51:47

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-18T18:51:43', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '9c762d2f-bfa3-450f-bcc0-b88d8920d54b'	System	18 Aug 2020 22:51:47
User entered '18 Aug 2020 18:51'	System	18 Aug 2020 22:51:47

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 7'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-19T18:32:18', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '7dfd8567-d926-46d4-b42c-7f046c86d070'	System	19 Aug 2020 22:32:37
User entered 'Yes (Y)'	System	19 Aug 2020 22:32:37

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-19T18:32:22', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '7dfd8567-d926-46d4-b42c-7f046c86d070'	System	19 Aug 2020 22:32:37
User entered '98.3'	System	19 Aug 2020 22:32:37

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-19T18:32:25', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '7dfd8567-d926-46d4-b42c-7f046c86d070'	System	19 Aug 2020 22:32:37
User entered 'Yes (Y)'	System	19 Aug 2020 22:32:37

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirm' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 05:58:19
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-19T18:32:31', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '7dfd8567-d926-46d4-b42c-7f046c86d070'	System	19 Aug 2020 22:32:37
User entered '1'	System	19 Aug 2020 22:32:37

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-19T18:32:31', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '7dfd8567-d926-46d4-b42c-7f046c86d070'	System	19 Aug 2020 22:32:37
User entered '0'	System	19 Aug 2020 22:32:37

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-19T18:32:34', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '7dfd8567-d926-46d4-b42c-7f046c86d070'	System	19 Aug 2020 22:32:37
User entered '19 Aug 2020 18:32'	System	19 Aug 2020 22:32:37

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 22:32:37
User entered 'Day 8'	System	19 Aug 2020 22:32:37

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 11:09:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-20T18:32:20', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '724f0dd6-dabd-4ccf-b376-5fcf6abf98d3'	System	20 Aug 2020 22:32:35
User entered 'Yes (Y)'	System	20 Aug 2020 22:32:35

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 11:09:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-20T18:32:24', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '724f0dd6-dabd-4ccf-b376-5fcf6abf98d3'	System	20 Aug 2020 22:32:35
User entered '98.5'	System	20 Aug 2020 22:32:35

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-20T18:32:27', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '724f0dd6-dabd-4ccf-b376-5fcf6abf98d3'	System	20 Aug 2020 22:32:35
User entered 'No (N)'	System	20 Aug 2020 22:32:35

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-20T18:32:31', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '724f0dd6-dabd-4ccf-b376-5fcf6abf98d3'	System	20 Aug 2020 22:32:35
User entered '20 Aug 2020 18:32'	System	20 Aug 2020 22:32:35

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 22:32:37

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 22:32:37

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-13T14:05:16', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '69b98174-5ea0-430e-afbb-aba3847ca992'	System	13 Aug 2020 18:05:50
User entered 'None (1)'	System	13 Aug 2020 18:05:50

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T14:05:25', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '69b98174-5ea0-430e-afbb-aba3847ca992'	System	13 Aug 2020 18:05:50
User entered 'No (N)'	System	13 Aug 2020 18:05:50

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T14:05:28', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '69b98174-5ea0-430e-afbb-aba3847ca992'	System	13 Aug 2020 18:05:50
User entered 'No (N)'	System	13 Aug 2020 18:05:50

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-13T14:05:39', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '69b98174-5ea0-430e-afbb-aba3847ca992'	System	13 Aug 2020 18:05:50
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 18:05:50

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T14:05:45', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '69b98174-5ea0-430e-afbb-aba3847ca992'	System	13 Aug 2020 18:05:50
User entered '13 Aug 2020 14:05'	System	13 Aug 2020 18:05:50

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 13:55'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 16:25'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-13T18:31:37', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '10f5a4b4-c6d1-4130-84d9-89fcf5b32c14'	System	13 Aug 2020 22:32:08
User entered 'None (1)'	System	13 Aug 2020 22:32:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T18:31:43', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '10f5a4b4-c6d1-4130-84d9-89fcf5b32c14'	System	13 Aug 2020 22:32:08
User entered 'No (N)'	System	13 Aug 2020 22:32:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T18:31:46', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '10f5a4b4-c6d1-4130-84d9-89fcf5b32c14'	System	13 Aug 2020 22:32:08
User entered 'No (N)'	System	13 Aug 2020 22:32:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-13T18:32:01', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '10f5a4b4-c6d1-4130-84d9-89fcf5b32c14'	System	13 Aug 2020 22:32:08
User entered 'None (1)'	System	13 Aug 2020 22:32:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T18:32:05', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '10f5a4b4-c6d1-4130-84d9-89fcf5b32c14'	System	13 Aug 2020 22:32:08
User entered '13 Aug 2020 18:32'	System	13 Aug 2020 22:32:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 17:20'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 2'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-14T19:27:01', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'dd4db9fd-4ce0-4ae7-b22e-d3cfe30ca6e6'	System	14 Aug 2020 23:27:41
User entered 'None (1)'	System	14 Aug 2020 23:27:41

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-14T19:27:09', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'dd4db9fd-4ce0-4ae7-b22e-d3cfe30ca6e6'	System	14 Aug 2020 23:27:41
User entered 'No (N)'	System	14 Aug 2020 23:27:41

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-14T19:27:21', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'dd4db9fd-4ce0-4ae7-b22e-d3cfe30ca6e6'	System	14 Aug 2020 23:27:41
User entered 'No (N)'	System	14 Aug 2020 23:27:41

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-14T19:27:32', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'dd4db9fd-4ce0-4ae7-b22e-d3cfe30ca6e6'	System	14 Aug 2020 23:27:41
User entered 'None (1)'	System	14 Aug 2020 23:27:41

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-14T19:27:38', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'dd4db9fd-4ce0-4ae7-b22e-d3cfe30ca6e6'	System	14 Aug 2020 23:27:41
User entered '14 Aug 2020 19:27'	System	14 Aug 2020 23:27:41

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 3'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-15T14:25:38', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'a3ef9eae-bdc5-4bc3-a85c-df235bc67935'	System	15 Aug 2020 18:26:05
User entered 'None (1)'	System	15 Aug 2020 18:26:05

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-15T14:25:43', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'a3ef9eae-bdc5-4bc3-a85c-df235bc67935'	System	15 Aug 2020 18:26:05
User entered 'No (N)'	System	15 Aug 2020 18:26:05

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-15T14:25:46', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'a3ef9eae-bdc5-4bc3-a85c-df235bc67935'	System	15 Aug 2020 18:26:05
User entered 'No (N)'	System	15 Aug 2020 18:26:05

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-15T14:25:58', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'a3ef9eae-bdc5-4bc3-a85c-df235bc67935'	System	15 Aug 2020 18:26:05
User entered 'None (1)'	System	15 Aug 2020 18:26:05

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-15T14:26:01', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'a3ef9eae-bdc5-4bc3-a85c-df235bc67935'	System	15 Aug 2020 18:26:05
User entered '15 Aug 2020 14:26'	System	15 Aug 2020 18:26:05

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 4'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-16T18:34:01', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'f01c8fd7-c3d4-439a-8fb3-aacd0680fd2d'	System	16 Aug 2020 22:34:29
User entered 'None (1)'	System	16 Aug 2020 22:34:29

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-16T18:34:04', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'f01c8fd7-c3d4-439a-8fb3-aacd0680fd2d'	System	16 Aug 2020 22:34:29
User entered 'No (N)'	System	16 Aug 2020 22:34:29

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-16T18:34:06', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'f01c8fd7-c3d4-439a-8fb3-aacd0680fd2d'	System	16 Aug 2020 22:34:29
User entered 'No (N)'	System	16 Aug 2020 22:34:29

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-16T18:34:17', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'f01c8fd7-c3d4-439a-8fb3-aacd0680fd2d'	System	16 Aug 2020 22:34:29
User entered 'None (1)'	System	16 Aug 2020 22:34:29

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-16T18:34:26', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'f01c8fd7-c3d4-439a-8fb3-aacd0680fd2d'	System	16 Aug 2020 22:34:29
User entered '16 Aug 2020 18:34'	System	16 Aug 2020 22:34:29

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 5'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-17T18:32:37', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '48fcf748-ac8d-4e14-9e32-946ad80c19ac'	System	17 Aug 2020 22:33:00
User entered 'None (1)'	System	17 Aug 2020 22:33:00

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-17T18:32:40', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '48fcf748-ac8d-4e14-9e32-946ad80c19ac'	System	17 Aug 2020 22:33:00
User entered 'No (N)'	System	17 Aug 2020 22:33:00

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-17T18:32:42', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '48fcf748-ac8d-4e14-9e32-946ad80c19ac'	System	17 Aug 2020 22:33:00
User entered 'No (N)'	System	17 Aug 2020 22:33:00

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-17T18:32:54', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '48fcf748-ac8d-4e14-9e32-946ad80c19ac'	System	17 Aug 2020 22:33:00
User entered 'None (1)'	System	17 Aug 2020 22:33:00

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-17T18:32:56', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '48fcf748-ac8d-4e14-9e32-946ad80c19ac'	System	17 Aug 2020 22:33:00
User entered '17 Aug 2020 18:32'	System	17 Aug 2020 22:33:00

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 6'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-18T18:51:48', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '7b4a79b4-a9d7-4dc5-9066-ce79a67b7535'	System	18 Aug 2020 22:52:35
User entered 'None (1)'	System	18 Aug 2020 22:52:35

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-18T18:51:51', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '7b4a79b4-a9d7-4dc5-9066-ce79a67b7535'	System	18 Aug 2020 22:52:35
User entered 'No (N)'	System	18 Aug 2020 22:52:35

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-18T18:51:55', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '7b4a79b4-a9d7-4dc5-9066-ce79a67b7535'	System	18 Aug 2020 22:52:35
User entered 'No (N)'	System	18 Aug 2020 22:52:35

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-18T18:52:30', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '7b4a79b4-a9d7-4dc5-9066-ce79a67b7535'	System	18 Aug 2020 22:52:35
User entered 'None (1)'	System	18 Aug 2020 22:52:35

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-18T18:52:32', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '7b4a79b4-a9d7-4dc5-9066-ce79a67b7535'	System	18 Aug 2020 22:52:35
User entered '18 Aug 2020 18:52'	System	18 Aug 2020 22:52:35

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 7'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:54

[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 (10f568eccf40e085)', Time: '2020-08-19T18:32:39', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '7706beac-436f-4c75-ba48-9d1806ec52c2'	System	19 Aug 2020 22:32:53
User entered 'None (1)'	System	19 Aug 2020 22:32:53

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-19T18:32:42', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '7706beac-436f-4c75-ba48-9d1806ec52c2'	System	19 Aug 2020 22:32:53
User entered 'No (N)'	System	19 Aug 2020 22:32:53

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-19T18:32:44', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '7706beac-436f-4c75-ba48-9d1806ec52c2'	System	19 Aug 2020 22:32:53
User entered 'No (N)'	System	19 Aug 2020 22:32:53

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-19T18:32:48', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '7706beac-436f-4c75-ba48-9d1806ec52c2'	System	19 Aug 2020 22:32:53
User entered 'None (1)'	System	19 Aug 2020 22:32:53

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-19T18:32:51', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '7706beac-436f-4c75-ba48-9d1806ec52c2'	System	19 Aug 2020 22:32:53
User entered '19 Aug 2020 18:32'	System	19 Aug 2020 22:32:53

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T14:05:54', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'bf1c707c-b436-41be-ac76-15f9186924f4'	System	13 Aug 2020 18:06:22
User entered 'None (0)'	System	13 Aug 2020 18:06:22

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T14:05:58', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'bf1c707c-b436-41be-ac76-15f9186924f4'	System	13 Aug 2020 18:06:22
User entered 'None (0)'	System	13 Aug 2020 18:06:22

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T14:06:01', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'bf1c707c-b436-41be-ac76-15f9186924f4'	System	13 Aug 2020 18:06:22
User entered 'None (0)'	System	13 Aug 2020 18:06:22

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T14:06:04', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'bf1c707c-b436-41be-ac76-15f9186924f4'	System	13 Aug 2020 18:06:22
User entered 'None (0)'	System	13 Aug 2020 18:06:22

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T14:06:06', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'bf1c707c-b436-41be-ac76-15f9186924f4'	System	13 Aug 2020 18:06:22
User entered 'None (0)'	System	13 Aug 2020 18:06:22

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T14:06:08', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'bf1c707c-b436-41be-ac76-15f9186924f4'	System	13 Aug 2020 18:06:22
User entered 'None (0)'	System	13 Aug 2020 18:06:22

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-13T14:06:15', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'bf1c707c-b436-41be-ac76-15f9186924f4'	System	13 Aug 2020 18:06:22
User entered 'No (N)'	System	13 Aug 2020 18:06:22

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T14:06:19', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'bf1c707c-b436-41be-ac76-15f9186924f4'	System	13 Aug 2020 18:06:22
User entered '13 Aug 2020 14:06'	System	13 Aug 2020 18:06:22

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 13:55'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 16:25'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T18:32:10', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '05774842-c9b0-4bb9-b8ee-fc7837838b88'	System	13 Aug 2020 22:32:31
User entered 'None (0)'	System	13 Aug 2020 22:32:31

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T18:32:13', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '05774842-c9b0-4bb9-b8ee-fc7837838b88'	System	13 Aug 2020 22:32:31
User entered 'None (0)'	System	13 Aug 2020 22:32:31

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T18:32:16', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '05774842-c9b0-4bb9-b8ee-fc7837838b88'	System	13 Aug 2020 22:32:31
User entered 'None (0)'	System	13 Aug 2020 22:32:31

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T18:32:18', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '05774842-c9b0-4bb9-b8ee-fc7837838b88'	System	13 Aug 2020 22:32:31
User entered 'None (0)'	System	13 Aug 2020 22:32:31

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T18:32:20', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '05774842-c9b0-4bb9-b8ee-fc7837838b88'	System	13 Aug 2020 22:32:31
User entered 'None (0)'	System	13 Aug 2020 22:32:31

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T18:32:21', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '05774842-c9b0-4bb9-b8ee-fc7837838b88'	System	13 Aug 2020 22:32:31
User entered 'None (0)'	System	13 Aug 2020 22:32:31

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-13T18:32:25', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '05774842-c9b0-4bb9-b8ee-fc7837838b88'	System	13 Aug 2020 22:32:31
User entered 'No (N)'	System	13 Aug 2020 22:32:31

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-13T18:32:29', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '05774842-c9b0-4bb9-b8ee-fc7837838b88'	System	13 Aug 2020 22:32:31
User entered '13 Aug 2020 18:32'	System	13 Aug 2020 22:32:31

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 17:20'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 2'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:54

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-14T19:27:42', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '85db3f8c-7c40-4f39-96cb-eac468081d12'	System	14 Aug 2020 23:28:08
User entered 'None (0)'	System	14 Aug 2020 23:28:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:54

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-14T19:27:47', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '85db3f8c-7c40-4f39-96cb-eac468081d12'	System	14 Aug 2020 23:28:08
User entered 'Some interference with activity (2)'	System	14 Aug 2020 23:28:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-14T19:27:50', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '85db3f8c-7c40-4f39-96cb-eac468081d12'	System	14 Aug 2020 23:28:08
User entered 'None (0)'	System	14 Aug 2020 23:28:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-14T19:27:52', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '85db3f8c-7c40-4f39-96cb-eac468081d12'	System	14 Aug 2020 23:28:08
User entered 'None (0)'	System	14 Aug 2020 23:28:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-14T19:27:54', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '85db3f8c-7c40-4f39-96cb-eac468081d12'	System	14 Aug 2020 23:28:08
User entered 'None (0)'	System	14 Aug 2020 23:28:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:54

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-14T19:27:56', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '85db3f8c-7c40-4f39-96cb-eac468081d12'	System	14 Aug 2020 23:28:08
User entered 'None (0)'	System	14 Aug 2020 23:28:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-14T19:28:00', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '85db3f8c-7c40-4f39-96cb-eac468081d12'	System	14 Aug 2020 23:28:08
User entered 'No (N)'	System	14 Aug 2020 23:28:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-14T19:28:05', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '85db3f8c-7c40-4f39-96cb-eac468081d12'	System	14 Aug 2020 23:28:08
User entered '14 Aug 2020 19:28'	System	14 Aug 2020 23:28:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 3'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:54

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-15T14:26:05', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'ed247c40-c8a8-4022-b49a-7b8fe8f113bf'	System	15 Aug 2020 18:26:21
User entered 'None (0)'	System	15 Aug 2020 18:26:21

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:54

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-15T14:26:07', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'ed247c40-c8a8-4022-b49a-7b8fe8f113bf'	System	15 Aug 2020 18:26:21
User entered 'None (0)'	System	15 Aug 2020 18:26:21

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-15T14:26:09', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'ed247c40-c8a8-4022-b49a-7b8fe8f113bf'	System	15 Aug 2020 18:26:21
User entered 'None (0)'	System	15 Aug 2020 18:26:21

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-15T14:26:10', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'ed247c40-c8a8-4022-b49a-7b8fe8f113bf'	System	15 Aug 2020 18:26:21
User entered 'None (0)'	System	15 Aug 2020 18:26:21

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-15T14:26:12', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'ed247c40-c8a8-4022-b49a-7b8fe8f113bf'	System	15 Aug 2020 18:26:21
User entered 'None (0)'	System	15 Aug 2020 18:26:21

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:54

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-15T14:26:13', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'ed247c40-c8a8-4022-b49a-7b8fe8f113bf'	System	15 Aug 2020 18:26:21
User entered 'None (0)'	System	15 Aug 2020 18:26:21

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-15T14:26:16', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'ed247c40-c8a8-4022-b49a-7b8fe8f113bf'	System	15 Aug 2020 18:26:21
User entered 'No (N)'	System	15 Aug 2020 18:26:21

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-15T14:26:19', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'ed247c40-c8a8-4022-b49a-7b8fe8f113bf'	System	15 Aug 2020 18:26:21
User entered '15 Aug 2020 14:26'	System	15 Aug 2020 18:26:21

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 4'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:54

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-16T18:34:57', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'bead6458-d35a-410a-aecb-55eb7c35f875'	System	16 Aug 2020 22:35:16
User entered 'Any use of prescription pain reliever or prevents daily activity (3)'	System	16 Aug 2020 22:35:16

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:54

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-16T18:34:59', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'bead6458-d35a-410a-aecb-55eb7c35f875'	System	16 Aug 2020 22:35:16
User entered 'None (0)'	System	16 Aug 2020 22:35:16

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-16T18:35:01', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'bead6458-d35a-410a-aecb-55eb7c35f875'	System	16 Aug 2020 22:35:16
User entered 'None (0)'	System	16 Aug 2020 22:35:16

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-16T18:35:02', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'bead6458-d35a-410a-aecb-55eb7c35f875'	System	16 Aug 2020 22:35:16
User entered 'None (0)'	System	16 Aug 2020 22:35:16

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-16T18:35:04', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'bead6458-d35a-410a-aecb-55eb7c35f875'	System	16 Aug 2020 22:35:16
User entered 'None (0)'	System	16 Aug 2020 22:35:16

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:54

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-16T18:35:06', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'bead6458-d35a-410a-aecb-55eb7c35f875'	System	16 Aug 2020 22:35:16
User entered 'None (0)'	System	16 Aug 2020 22:35:16

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-16T18:35:08', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'bead6458-d35a-410a-aecb-55eb7c35f875'	System	16 Aug 2020 22:35:16
User entered 'No (N)'	System	16 Aug 2020 22:35:16

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-16T18:35:11', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'bead6458-d35a-410a-aecb-55eb7c35f875'	System	16 Aug 2020 22:35:16
User entered '16 Aug 2020 18:35'	System	16 Aug 2020 22:35:16

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 5'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:54

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-17T18:33:00', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '92d686c7-8bd5-4289-854e-f6914ea53033'	System	17 Aug 2020 22:33:22
User entered 'None (0)'	System	17 Aug 2020 22:33:22

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:54

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-17T18:33:05', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '92d686c7-8bd5-4289-854e-f6914ea53033'	System	17 Aug 2020 22:33:22
User entered 'Some interference with activity (2)'	System	17 Aug 2020 22:33:22

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-17T18:33:08', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '92d686c7-8bd5-4289-854e-f6914ea53033'	System	17 Aug 2020 22:33:22
User entered 'None (0)'	System	17 Aug 2020 22:33:22

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-17T18:33:11', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '92d686c7-8bd5-4289-854e-f6914ea53033'	System	17 Aug 2020 22:33:22
User entered 'None (0)'	System	17 Aug 2020 22:33:22

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-17T18:33:13', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '92d686c7-8bd5-4289-854e-f6914ea53033'	System	17 Aug 2020 22:33:22
User entered 'None (0)'	System	17 Aug 2020 22:33:22

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:54

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-17T18:33:14', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '92d686c7-8bd5-4289-854e-f6914ea53033'	System	17 Aug 2020 22:33:22
User entered 'None (0)'	System	17 Aug 2020 22:33:22

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-17T18:33:17', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '92d686c7-8bd5-4289-854e-f6914ea53033'	System	17 Aug 2020 22:33:22
User entered 'No (N)'	System	17 Aug 2020 22:33:22

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-17T18:33:19', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '92d686c7-8bd5-4289-854e-f6914ea53033'	System	17 Aug 2020 22:33:22
User entered '17 Aug 2020 18:33'	System	17 Aug 2020 22:33:22

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 6'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:54

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-18T18:52:39', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '8a085897-1e74-4bb3-8ac3-1f71d954e8b7'	System	18 Aug 2020 22:54:07
User entered 'No interference with activity (1)'	System	18 Aug 2020 22:54:07

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:54

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-18T18:53:53', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '8a085897-1e74-4bb3-8ac3-1f71d954e8b7'	System	18 Aug 2020 22:54:07
User entered 'None (0)'	System	18 Aug 2020 22:54:07

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-18T18:53:55', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '8a085897-1e74-4bb3-8ac3-1f71d954e8b7'	System	18 Aug 2020 22:54:07
User entered 'None (0)'	System	18 Aug 2020 22:54:07

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-18T18:53:56', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '8a085897-1e74-4bb3-8ac3-1f71d954e8b7'	System	18 Aug 2020 22:54:07
User entered 'None (0)'	System	18 Aug 2020 22:54:07

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-18T18:53:58', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '8a085897-1e74-4bb3-8ac3-1f71d954e8b7'	System	18 Aug 2020 22:54:07
User entered 'None (0)'	System	18 Aug 2020 22:54:07

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:54

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-18T18:53:59', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '8a085897-1e74-4bb3-8ac3-1f71d954e8b7'	System	18 Aug 2020 22:54:07
User entered 'None (0)'	System	18 Aug 2020 22:54:07

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-18T18:54:02', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '8a085897-1e74-4bb3-8ac3-1f71d954e8b7'	System	18 Aug 2020 22:54:07
User entered 'No (N)'	System	18 Aug 2020 22:54:07

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-18T18:54:04', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '8a085897-1e74-4bb3-8ac3-1f71d954e8b7'	System	18 Aug 2020 22:54:07
User entered '18 Aug 2020 18:54'	System	18 Aug 2020 22:54:07

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 7'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:54

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-19T18:33:06', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'b6ded545-365c-4924-bc83-56ed65158422'	System	19 Aug 2020 22:33:34
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	19 Aug 2020 22:33:34

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:54

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-19T18:33:14', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'b6ded545-365c-4924-bc83-56ed65158422'	System	19 Aug 2020 22:33:34
User entered 'Some interference with activity (2)'	System	19 Aug 2020 22:33:34

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-19T18:33:16', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'b6ded545-365c-4924-bc83-56ed65158422'	System	19 Aug 2020 22:33:34
User entered 'None (0)'	System	19 Aug 2020 22:33:34

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-19T18:33:19', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'b6ded545-365c-4924-bc83-56ed65158422'	System	19 Aug 2020 22:33:34
User entered 'None (0)'	System	19 Aug 2020 22:33:34

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-19T18:33:21', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'b6ded545-365c-4924-bc83-56ed65158422'	System	19 Aug 2020 22:33:34
User entered 'None (0)'	System	19 Aug 2020 22:33:34

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:54

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-19T18:33:23', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'b6ded545-365c-4924-bc83-56ed65158422'	System	19 Aug 2020 22:33:34
User entered 'None (0)'	System	19 Aug 2020 22:33:34

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-19T18:33:26', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'b6ded545-365c-4924-bc83-56ed65158422'	System	19 Aug 2020 22:33:34
User entered 'No (N)'	System	19 Aug 2020 22:33:34

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-19T18:33:29', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'b6ded545-365c-4924-bc83-56ed65158422'	System	19 Aug 2020 22:33:34
User entered '19 Aug 2020 18:33'	System	19 Aug 2020 22:33:34

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 22:54:07
User entered 'Day 8'	System	18 Aug 2020 22:54:07

US3672097

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 11:09:54

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-20T18:32:38', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '939ff359-78a0-49a5-988b-e54f35884647'	System	20 Aug 2020 22:32:45
User entered 'None (0)'	System	20 Aug 2020 22:32:45

US3672097

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-20T18:32:41', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '939ff359-78a0-49a5-988b-e54f35884647'	System	20 Aug 2020 22:32:45
User entered '20 Aug 2020 18:32'	System	20 Aug 2020 22:32:45

US3672097

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 22:54:07

US3672097

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 22:54:07

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 22:33:34
User entered 'Day 8'	System	19 Aug 2020 22:33:34

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:09:54

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-20T18:32:45', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'd3707b60-1636-42b7-9d80-a1b5f7145c94'	System	20 Aug 2020 22:32:50
User entered 'Some interference with activity (2)'	System	20 Aug 2020 22:32:50

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-20T18:32:48', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'd3707b60-1636-42b7-9d80-a1b5f7145c94'	System	20 Aug 2020 22:32:50
User entered '20 Aug 2020 18:32'	System	20 Aug 2020 22:32:50

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 22:33:34

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 22:33:34

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 22:33:34
User entered 'Day 9'	System	19 Aug 2020 22:33:34

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:09:54

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-21T18:36:20', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '1fc5d5f5-cda2-4701-bc48-11684ca9446a'	System	21 Aug 2020 22:36:31
User entered 'Some interference with activity (2)'	System	21 Aug 2020 22:36:31

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-21T18:36:27', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '1fc5d5f5-cda2-4701-bc48-11684ca9446a'	System	21 Aug 2020 22:36:31
User entered '21 Aug 2020 18:36'	System	21 Aug 2020 22:36:31

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 22:33:34

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 22:33:34

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 22:32:50
User entered 'Day 10'	System	20 Aug 2020 22:32:50

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:09:54

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-22T18:41:03', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '93706909-00ee-4c96-90cf-7a8215851367'	System	22 Aug 2020 22:41:08
User entered 'Some interference with activity (2)'	System	22 Aug 2020 22:41:08

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-22T18:41:06', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '93706909-00ee-4c96-90cf-7a8215851367'	System	22 Aug 2020 22:41:08
User entered '22 Aug 2020 18:41'	System	22 Aug 2020 22:41:08

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 22:32:50

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 22:32:50

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 22:36:31
User entered 'Day 11'	System	21 Aug 2020 22:36:31

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 11:09:54

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-23T18:55:29', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'e4875c62-1cfb-498b-aa78-ffdc61edc4d4'	System	23 Aug 2020 22:55:36
User entered 'None (0)'	System	23 Aug 2020 22:55:36

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 11:09:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-23T18:55:32', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'e4875c62-1cfb-498b-aa78-ffdc61edc4d4'	System	23 Aug 2020 22:55:36
User entered '23 Aug 2020 18:55'	System	23 Aug 2020 22:55:36

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 22:36:31

US3672097

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 22:36:31

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 22:54:07
User entered 'Day 8'	System	18 Aug 2020 22:54:07

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-20T18:32:51', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '6941b9c6-e17c-42be-aacb-2c35ece1af01'	System	20 Aug 2020 22:32:57
User entered 'No (N)'	System	20 Aug 2020 22:32:57

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:09:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-20T18:32:53', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '6941b9c6-e17c-42be-aacb-2c35ece1af01'	System	20 Aug 2020 22:32:57
User entered '20 Aug 2020 18:32'	System	20 Aug 2020 22:32:57

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 22:54:07

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 22:54:07

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	20 Aug 2020 22:32:50
DataPoint Inactivated.	System	20 Aug 2020 22:32:45
Data entry locked.	System	19 Aug 2020 22:32:37
User entered 'Day 9'	System	19 Aug 2020 22:32:37

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-21T18:36:31', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '822931db-e345-4633-95e6-472c6a6016a1'	System	21 Aug 2020 22:36:37
User entered 'No (N)'	System	21 Aug 2020 22:36:37
DataPoint Activated.	System	20 Aug 2020 22:32:50
DataPoint Inactivated.	System	20 Aug 2020 22:32:45

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:09:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-21T18:36:34', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '822931db-e345-4633-95e6-472c6a6016a1'	System	21 Aug 2020 22:36:37
User entered '21 Aug 2020 18:36'	System	21 Aug 2020 22:36:37
DataPoint Activated.	System	20 Aug 2020 22:32:50
DataPoint Inactivated.	System	20 Aug 2020 22:32:45

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	20 Aug 2020 22:32:50
DataPoint Inactivated.	System	20 Aug 2020 22:32:45
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 22:32:37

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	20 Aug 2020 22:32:50
DataPoint Inactivated.	System	20 Aug 2020 22:32:45
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 22:32:37

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 22:32:50
User entered 'Day 10'	System	20 Aug 2020 22:32:50

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-22T18:41:10', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '9c8d3e69-bba4-420b-99ac-584d9de26070'	System	22 Aug 2020 22:41:14
User entered 'No (N)'	System	22 Aug 2020 22:41:14

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:09:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-22T18:41:12', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '9c8d3e69-bba4-420b-99ac-584d9de26070'	System	22 Aug 2020 22:41:14
User entered '22 Aug 2020 18:41'	System	22 Aug 2020 22:41:14

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 22:32:50

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 22:32:50

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 22:36:31
User entered 'Day 11'	System	21 Aug 2020 22:36:31

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-08-23T18:55:35', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'cc76b737-89d7-4cf9-a10c-cb1ec40d6a15'	System	23 Aug 2020 22:55:41
User entered 'No (N)'	System	23 Aug 2020 22:55:41

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:09:54

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-08-23T18:55:37', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'cc76b737-89d7-4cf9-a10c-cb1ec40d6a15'	System	23 Aug 2020 22:55:41
User entered '23 Aug 2020 18:55'	System	23 Aug 2020 22:55:41

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:09:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 22:36:31

US3672097

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:09:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 22:36:31

US3672097

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:05:14

US3672097

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 18:05:14

US3672097

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Aug 2020 18:05:14

US3672097

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:05:14

US3672097

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:05:18

US3672097

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:05:18

US3672097

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 17:13:45

US3672097

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 09:30:37
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	(b) (4), (b) (6)	31 Aug 2020 17:13:53
answered with 'added pd due to subject being oow' (Site from System).		
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	31 Aug 2020 17:13:45
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 17:13:45

US3672097

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	31 Aug 2020 17:13:45

US3672097

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 17:13:45

US3672097

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 17:13:57

US3672097

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 17:13:57

US3672097

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:19:24

US3672097

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '03 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 19:19:24

US3672097

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Sep 2020 19:19:24

US3672097

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:19:24

US3672097

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:19:28

US3672097

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:19:28

US3672097

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'Per CDM: Was this visit performed? = No, however, Continuing page = Yes. Please update or clarify accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:59:37
User opened query 'Per CDM: Was this visit performed? = No, however, Continuing page = Yes. Please update or clarify accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:58:12
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 14:36:58

US3672097

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:36:58

US3672097

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:36:58

US3672097

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	23 Sep 2020 14:36:58

US3672097

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:37:04

US3672097

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:37:04

US3672097

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 13:13:47

US3672097

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 13:13:47

US3672097

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 13:13:47

US3672097

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'on illness track'	(b) (4), (b) (6)	16 Oct 2020 13:13:47

US3672097

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:29:00

US3672097

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 19:29:00

US3672097

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 13:13:53

US3672097

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 13:13:53

US3672097

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 13:13:53

US3672097

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'on illness track'	(b) (4), (b) (6)	16 Oct 2020 13:13:53

US3672097

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:29:09

US3672097

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 19:29:09

US3672097

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 13:13:04

US3672097

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 13:13:04

US3672097

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 13:13:04

US3672097

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'on illness track'	(b) (4), (b) (6)	16 Oct 2020 13:13:04

US3672097

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:29:18

US3672097

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 19:29:18

US3672097

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:29:29

US3672097

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Patty Howenstine (b) (4)	13 Oct 2020 19:29:29
	(b) (4)	

US3672097

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:29:29

US3672097

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	13 Oct 2020 19:29:29

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	13 Oct 2020 19:30:31
	(b) (4)	

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '13:10'	Patty Howenstine (b) (4)	13 Oct 2020 19:30:31
	(b) (4)	

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 13:10'	System	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	Patty Howenstine (b) (4)	13 Oct 2020 19:30:31
	(b) (4)	

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Pulse (xxx)

Audit	User	Time (GMT)
User entered '68'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '15'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '124'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '79'	Patty Howenstine (b) (4)	13 Oct 2020 19:30:31
	(b) (4)	

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:54

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:30:34

US3672097

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:30:34

US3672097

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:29:59

US3672097

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:29:59

US3672097

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '13:35'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:29:59

US3672097

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 13:35'	System	13 Oct 2020 19:29:59

US3672097

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:30:03

US3672097

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 19:30:03

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 64'	System	13 Aug 2020 17:55:08

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

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 (10f568eccf40e085)', Time: '2020-10-13T14:36:02', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '1870422e-9524-43c8-b3e4-8c92a59cf752'	System	13 Oct 2020 18:36:17
User entered 'No (N)'	System	13 Oct 2020 18:36:17

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

Have you been exposed to someone with 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 (10f568eccf40e085)', Time: '2020-10-13T14:36:07', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '1870422e-9524-43c8-b3e4-8c92a59cf752'	System	13 Oct 2020 18:36:17
User entered 'No (N)'	System	13 Oct 2020 18:36:17

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-10-13T14:36:13', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '1870422e-9524-43c8-b3e4-8c92a59cf752'	System	13 Oct 2020 18:36:17
User entered '13 Oct 2020 14:36:13'	System	13 Oct 2020 18:36:17

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 17:55:08

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 92'	System	13 Aug 2020 17:55:08

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[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 (10f568eccf40e085)', Time: '2020-11-13T19:52:57', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'c57a9eb4-fd8b-4835-b3c2-a7194de28e0e'	System	14 Nov 2020 00:53:12
User entered 'No (N)'	System	14 Nov 2020 00:53:12

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

Have you been exposed to someone with 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 (10f568eccf40e085)', Time: '2020-11-13T19:53:03', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'c57a9eb4-fd8b-4835-b3c2-a7194de28e0e'	System	14 Nov 2020 00:53:12
User entered 'No (N)'	System	14 Nov 2020 00:53:12

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-11-13T19:53:09', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'c57a9eb4-fd8b-4835-b3c2-a7194de28e0e'	System	14 Nov 2020 00:53:12
User entered '13 Nov 2020 19:53:09'	System	14 Nov 2020 00:53:12

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 17:55:08

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 17:55:08
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 17:55:08

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '10 Oct 2020 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '14 Oct 2020 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '17 Oct 2020 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '21 Oct 2020 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '24 Oct 2020 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '28 Oct 2020 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '31 Oct 2020 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '04 Nov 2020 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '07 Nov 2020 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '11 Nov 2020 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '14 Nov 2020 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '18 Nov 2020 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:16:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:16:46
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 14:42:38

US3672097

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '9 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 14:42:38

US3672097

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Nov 2020 14:42:38

US3672097

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 14:42:38

US3672097

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 14:42:43

US3672097

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 14:42:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:54

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:39:50
User entered '11 Sep 2020'	Patty Howenstine (b) (4)	15 Sep 2020 14:19:16
	(b) (4)	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:54

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:39:50
User entered '12:30'	Patty Howenstine (b) (4)	15 Sep 2020 14:19:16
	(b) (4)	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:54

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:30'	System	15 Sep 2020 14:19:16

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:54

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:39:50
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Patty Howenstine (b) (4)	15 Sep 2020 14:19:16

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:54

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:39:50
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	15 Sep 2020 14:19:16

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Patty Howenstine (b) (4) (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[Date](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please confirm initial start date of symptoms and Contact date are the same (11SEP2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:31:53
Query 'Per CDM: Please confirm initial start date of symptoms and Contact date are the same (11SEP2020) or update accordingly' answered with 'confirm' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 21:03:42
User opened query 'Per CDM: Please confirm initial start date of symptoms and Contact date are the same (11SEP2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:52:46
User closed query 'Per ETRTR: Please complete data entry for other days in Symptoms log, pending data in Illness Visit folder and Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 13:36:32
Query 'Per ETRTR: Please complete data entry for other days in Symptoms log, pending data in Illness Visit folder and Saliva Collection page, thanks.' answered with 'inadvertently listed under separate days. one entry for each day' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 17:43:32
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User opened query 'Per ETRTR: Please complete data entry for other days in Symptoms log, pending data in Illness Visit folder and Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 17:40:04
User entered '11 Sep 2020'	Patty Howenstine (b) (4) (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User entered '0'	Patty Howenstine (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User entered '99'	Patty Howenstine (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:24:53
User closed query 'Per source, the Temperature is 98.8. please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 15:24:52
Query 'Per source, the Temperature is 98.8. please verify and update accordingly.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 17:43:53
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 17:43:47
User entered '98.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 17:43:47
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User opened query 'Per source, the Temperature is 98.8. please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 12:42:00
User entered '98.3' F	Patty Howenstine (b) (4) (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User entered 'None (None)'	Patty Howenstine (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:24:57
User closed query 'Per source, subjected reported "NONE" for cough. Please verify and update accordingly' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 15:24:56
Query 'Per source, subjected reported "NONE" for cough. Please verify and update accordingly' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 17:44:36
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 17:44:25
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 17:44:25
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User opened query 'Per source, subjected reported "NONE" for cough. Please verify and update accordingly' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 12:43:22
User entered 'Mild (Mild)'	Patty Howenstine (b) (4) (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User entered 'None (None)'	Patty Howenstine (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User entered 'None (None)'	Patty Howenstine (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

Fatigue

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:25:03
User closed query 'Per source, subject reported "Mild" for fatigue. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 15:25:01
Query 'Per source, subject reported "Mild" for fatigue. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 17:44:39
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 17:44:25
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 17:44:25
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User opened query 'Per source, subject reported "Mild" for fatigue. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 12:44:18
User entered 'None (None)'	Patty Howenstine (b) (4) (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User entered 'None (None)'	Patty Howenstine (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User entered 'None (None)'	Patty Howenstine (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:25:08
User closed query 'Per source, subject reported "Mild" for HA. Please verify and update accordingly' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 15:25:06
Query 'Per source, subject reported "Mild" for HA. Please verify and update accordingly' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 17:44:42
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 17:44:25
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 17:44:25
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User opened query 'Per source, subject reported "Mild" for HA. Please verify and update accordingly' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 12:45:03
User entered 'None (None)'	Patty Howenstine (b) (4) (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User entered 'Mild (Mild)'	Patty Howenstine (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User entered 'Mild (Mild)'	Patty Howenstine (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:25:12
User closed query 'Per source, subject reported "NONE" for nasal congestion. Please verify and update accordingly' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 15:25:10
Query 'Per source, subject reported "NONE" for nasal congestion. Please verify and update accordingly' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 17:44:45
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 17:44:25
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 17:44:25
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User opened query 'Per source, subject reported "NONE" for nasal congestion. Please verify and update accordingly' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 12:45:57
User entered 'Mild (Mild)'	Patty Howenstine (b) (4) (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User entered 'None (None)'	Patty Howenstine (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User entered 'None (None)'	Patty Howenstine (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User entered 'None (None)'	Patty Howenstine (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User entered 'None (None)'	Patty Howenstine (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:54

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:46:23
User entered 'Mild (Mild)'	Patty Howenstine (b) (4)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:13
User entered '12 Sep 2020'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:12
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:10
User entered '99'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:09
User entered '98.3' F	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:04
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:06
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:08
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:03
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:01
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:00
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:58:57
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:58:55
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:58:53
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:58:51
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:58:48
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:58:49
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:58:45
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:58:43
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:58:42
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:54

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:58:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:27
User entered '13 Sep 2020'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:32
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:34
User entered '99'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:39
User entered '98.3' F	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:51
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:50
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:59:48
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:00:10
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:00:12
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:00:09
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:00:07
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:00:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:00:25
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:00:23
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:00:39
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:00:41
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:00:42
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:00:43
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:54

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:00:38
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:01:05
User entered '14 Sep 2020'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:01:08
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:01:09
User entered '95'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:01:13
User entered '97.2' F	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:01:17
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:01:18
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:01:23
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:01:21
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:01:45
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:01:47
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:01:44
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:01:58
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:01:59
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:02:01
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:01:55
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:02:24
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:02:22
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:02:20
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:02:19
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:54

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:02:17
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:02:57
User entered '15 Sep 2020'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:02:59
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '100'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '97.3' F	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:54

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '16 Sep 2020'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '100'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '98.3' F	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:54

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '17 Sep 2020'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '100'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '97.3' F	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:54

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '18 Sep 2020'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '100'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '97.3' F	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:54

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '19 Sep 2020'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '100'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '97.0' F	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:54

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '20 Sep 2020'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '100'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '97.0' F	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:54

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '95'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '97.0' F	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:54

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '22 Sep 2020'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '99'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '95.2' F	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:54

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '23 Sep 2020'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '95'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '97.6' F	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:54

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Date](#)

Audit	User	Time (GMT)
Query 'Per CDM: It appears there may be additional records missing as a Convalescence Visit Day 28 is recorded with a date of 13OCT2020. Please reconcile or clarify' canceled (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:21:51
User opened query 'Per CDM: It appears there may be additional records missing as a Convalescence Visit Day 28 is recorded with a date of 13OCT2020. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:54:10
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '24 Sep 2020'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '99'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered '97.6' F	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:54

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:08:52
User entered 'None (None)'	(b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:54

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:48:55
User entered '11 Sep 2020'	Patty Howenstine (b) (4)	15 Sep 2020 14:23:56
	(b) (4)	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:54

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:48:55
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	15 Sep 2020 14:23:56

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:54

[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)	30 Oct 2020 17:41:12
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 'updated' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 13:22:43
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:22:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 13:22:37
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	01 Oct 2020 13:22:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 13:22:37
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 20:52:42
User entered empty; reason for change Data Entry Error	Patty Howenstine (b) (4)	17 Sep 2020 20:52:42
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 14:24:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 14:24:07
User entered 'No (N)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	15 Sep 2020 14:24:07
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 14:23:56
User entered empty.	Patty Howenstine (b) (4)	15 Sep 2020 14:23:56

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:54

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:48:55
User entered '11 Sep 2020'	Patty Howenstine (b) (4)	15 Sep 2020 14:23:56
	(b) (4)	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:54

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:48:55
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Patty Howenstine (b) (4)	15 Sep 2020 14:23:56

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:54

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:48:55
User entered empty.	Patty Howenstine (b) (4)	15 Sep 2020 14:23:56
	(b) (4)	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:54

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:48:55
User entered 'No (N)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	17 Sep 2020 20:52:33
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	15 Sep 2020 14:23:56

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:54

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:48:55
User entered empty; reason for change Data Entry Error	Patty Howenstine (b) (4)	17 Sep 2020 20:52:33
User entered 'Sent out per study protocol'	Patty Howenstine (b) (4)	15 Sep 2020 14:23:56

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:54

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:48:55
User entered empty; reason for change Data Entry Error	Patty Howenstine (b) (4)	17 Sep 2020 20:52:33
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	15 Sep 2020 14:23:56

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:54

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 13:22:37
User entered '0'	System	15 Sep 2020 14:24:07

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 17:42:34
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User closed query 'Please complete this page per source. Thanks' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 15:26:39
Query 'Please complete this page per source. Thanks' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 17:46:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 17:46:27
User opened query 'Please complete this page per source. Thanks' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 12:50:14
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 13:24:00
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:23:43
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 17:42:44
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 17:46:27
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 13:24:04
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:23:43
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

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)	20 Oct 2020 15:26:41
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 17:43:09
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 13:24:09
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:23:43
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:24:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 13:24:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 13:24:15
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:23:43
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:54

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:09:54

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:51:42
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	15 Sep 2020 13:37:56

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:09:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:09:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:46:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:09:54

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon: Re-query: Saliva: Response noted, however please confirm the sample collection date for Day 3. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 04:20:56
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 13SEP2020 for Day 3 is recorded in EDC, however same is reported with 10SEP2020 for Day 3 in PPD Central lab. Please confirm the correct date and update if applicable, thank you' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 04:20:56
Query 'Per GCL Lab Recon: Saliva: Sample dated 13SEP2020 for Day 3 is recorded in EDC, however same is reported with 10SEP2020 for Day 3 in PPD Central lab. Please confirm the correct date and update if applicable, thank you' answered with 'error is made by PPD lab, site cannot reconcile lab date.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 21:06:23
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 13SEP2020 for Day 3 is recorded in EDC, however same is reported with 10SEP2020 for Day 3 in PPD Central lab. Please confirm the correct date and update if applicable, thank you' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:16:08
Query 'Per GCL Lab Recon: Saliva: Sample dated 13SEP2020 for Day 3 is recorded in EDC central lab, however same is reported with 10SEP2020 for Day 3 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:15:53
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 13SEP2020 for Day 3 is recorded in EDC central lab, however same is reported with 10SEP2020 for Day 3 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 09:50:08
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:46:06
User entered '13 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:09:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:09:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:43:00
Query 'Per source, Saliva was not collected. please verify and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:37:49
User opened query 'Per source, Saliva was not collected. please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 13:51:58
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 13:51:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:49:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:09:54

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:43:06
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 13:52:04
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:52:02
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 13:51:18
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:49:34
User entered '15 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:09:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:09:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:43:15
Query 'Per source, Saliva was not collected. please verify and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:43:13
User opened query 'Per source, Saliva was not collected. please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 13:52:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:09:54

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:43:19
User entered '17 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:09:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:09:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:43:29
Query 'Per source, Saliva was not collected. please verify and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:43:24
User opened query 'Per source, Saliva was not collected. please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 13:53:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:09:54

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:43:31
User entered '19 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:09:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:09:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:44:12
Query 'Per source, Saliva was not collected. please verify and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:44:08
User opened query 'Per source, Saliva was not collected. please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 13:53:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:09:54

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:44:13
User entered '24 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:09:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:09:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:45:03
Query 'Per source, Saliva was not collected. please verify and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:44:35
User opened query 'Per source, Saliva was not collected. please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 13:53:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:09:54

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:45:04
User entered '1 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:09:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:09:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:41:26
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 19:28:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 19:28:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	13 Oct 2020 19:28:21
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 20:32:09
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:09:54

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13OCT2020 is recorded as Illness Visit Day28 in EDC, however the same is reported under COVID PCR Saliva visit in PPD Central lab. Please confirm the correct Visit and update if applicable, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 04:36:36
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13OCT2020 is recorded as Illness Visit Day28 in EDC, however the same is reported under COVID PCR Saliva visit in PPD Central lab. Please confirm the correct Visit and update if applicable, thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 09:48:42
	(b) (4), (b) (6)	04 Nov 2020 13:41:29
User entered '13 Oct 2020' reason for change: Data Entry Error	Patty Howenstine (b) (4)	13 Oct 2020 19:28:21
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:51:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 20:20:52

US3672097

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:51:59
User entered '11 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 20:20:52

US3672097

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:51:59
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Oct 2020 20:20:52

US3672097

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	08 Oct 2020 20:20:52

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:52:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:52:06
User entered '11 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:52:06
User entered '12:40'	(b) (4), (b) (6)	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:40'	System	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:52:06
User entered '165.4' cm	(b) (4), (b) (6)	08 Oct 2020 20:28:46
DataPoint set to visible.	System	08 Oct 2020 20:20:52

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:52:06
User entered '95.4' kg	(b) (4), (b) (6)	08 Oct 2020 20:28:46
DataPoint set to visible.	System	08 Oct 2020 20:20:52

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:52:06
User entered '98.8' F	(b) (4), (b) (6)	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:52:06
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:52:06
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:52:06
User entered '83'	(b) (4), (b) (6)	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:52:06
User entered '16'	(b) (4), (b) (6)	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:52:06
User entered '111'	(b) (4), (b) (6)	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:52:06
User entered '86'	(b) (4), (b) (6)	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:52:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 20:29:04

US3672097

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:52:11
User entered '11 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 20:29:04

US3672097

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:09:54

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:52:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 20:29:19

US3672097

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:09:54

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:52:15
User entered '11 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 20:29:19

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:38:34
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	13 Oct 2020 19:23:26

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:38:34
User entered '13 Oct 2020'	Patty Howenstine (b) (4)	13 Oct 2020 19:23:26
	(b) (4)	

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:38:34
User entered 'Clinic (Clinic)'	Patty Howenstine (b) (4)	13 Oct 2020 19:23:26

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:54

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	13 Oct 2020 19:23:26

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered '13 Oct 2020'	Patty Howenstine (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered '13:10'	Patty Howenstine (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 13:10'	System	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered '163.8' cm	Patty Howenstine (b) (4)	13 Oct 2020 19:27:54
DataPoint set to visible.	(b) (4) System	13 Oct 2020 19:23:26

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered '97.6' kg	Patty Howenstine (b) (4)	13 Oct 2020 19:27:54
DataPoint set to visible.	(b) (4) System	13 Oct 2020 19:23:26

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered '98.1' F	Patty Howenstine (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered 'Oral (Oral)'	Patty Howenstine (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered empty.	Patty Howenstine (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered '68'	Patty Howenstine (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered '15'	Patty Howenstine (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered '124'	Patty Howenstine (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered '79'	Patty Howenstine (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:40:59
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	13 Oct 2020 19:28:03

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:40:59
User entered '13 Oct 2020'	Patty Howenstine (b) (4)	13 Oct 2020 19:28:03
	(b) (4)	

US3672097

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:09:54

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:41:09
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	13 Oct 2020 19:28:08

US3672097

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:09:54

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:41:09
User entered '13 Oct 2020'	Patty Howenstine (b) (4)	13 Oct 2020 19:28:08
	(b) (4)	

US3672097

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:09:54

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:52:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 20:11:35

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:02:33
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:07:23
User entered 'USA-US116-2020-mRNA-1273-P301000002'	System	20 Sep 2020 18:07:18
User entered 'New'	(b) (4), (b) (6)	20 Sep 2020 18:07:18

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:47
User closed query 'Per CDM: Pleas consider updating term to COVID-19' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:14:27
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)	18 Nov 2020 21:15:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:15:48
Data point term sent to Coder	System	18 Nov 2020 21:14:37
Query 'Per CDM: Pleas consider updating term to COVID-19' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 21:14:10
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 21:14:04
Coding entries removed.	(b) (4), (b) (6)	18 Nov 2020 21:14:04
User entered 'COVID-19' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 21:14:04
User opened query 'Per CDM: Pleas consider updating term to COVID-19' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:31:39
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:02:35
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)	19 Sep 2020 07:17:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 07:17:42
Data point term sent to Coder	System	18 Sep 2020 20:13:23
User entered 'Covid'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:02:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:02:38
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:02:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Please update the start date to 11Sep2020' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 15:19:52
User closed query 'PV Query: Please clarify start date of 07 Sep 2020. On this date, the subject did not have any reported symptoms or a positive COVID-19 test. Please update start date to date of onset of signs and symptoms or positive test, whichever came first. If date is correct as reported, please provide additional details.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:07:30
Query 'PV Query: Please clarify start date of 07 Sep 2020. On this date, the subject did not have any reported symptoms or a positive COVID-19 test. Please update start date to date of onset of signs and symptoms or positive test, whichever came first. If date is correct as reported, please provide additional details.' answered with 'per progress note this was the start date' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:43:56
Query 'Please update the start date to 11Sep2020' answered with 'see above' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 13:43:40
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:07:07
User opened query 'Please update the start date to 11Sep2020' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 13:03:37
User opened query 'PV Query: Please clarify start date of 07 Sep 2020. On this date, the subject did not have any reported symptoms or a positive COVID-19 test. Please update start date to date of onset of signs and symptoms or positive test, whichever came first. If date is correct as reported, please provide additional details.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 16:55:51
User entered '7 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:03:40
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:32:07
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Nov 2020 20:47:06
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 20:47:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 20:47:06
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Nov 2020 20:46:59
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:03:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:32:09
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 20:46:59
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 20:46:59
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:03:44
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:03:46
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available.' canceled (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 19:57:04
User opened query 'PV Query: Please provide the event end date, when available.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 16:56:21
User entered empty.	System	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:03:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:06:11
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:03:59
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:04:00
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:04:02
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:04:08
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:04:10
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:04:11
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:04:13
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:04:14
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:04:24
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:04:17
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:20:23
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:07:42
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:47:52
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 13:47:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 13:47:38
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 13:47:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 13:47:38
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:07:07
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 18:07:10
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:12:40
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:20:21
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 13:47:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 13:47:38
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 13:47:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 13:47:38
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:07:05
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:12:40
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

Action taken with investigational product

Audit	User	Time (GMT)
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 'Reason for dosing discontinuation updated' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 21:04:42
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	24 Nov 2020 20:14:43
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)	03 Nov 2020 09:00:22
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:45:06
' answered with 'dosing discontinuation completed' (Site from DM).		
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 09:28:45
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:20:19
User closed query 'Per MM: Please provide the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 19:05:30

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide action taken with study drug. Per protocol, if a subject has a positive COVID-19 result prior to second vaccination dosing, study drug should be withdrawn. Please update action taken accordingly. ' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:07:48
Query 'Per MM: Please provide the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 13:48:01
Query 'PV Query: Please provide action taken with study drug. Per protocol, if a subject has a positive COVID-19 result prior to second vaccination dosing, study drug should be withdrawn. Please update action taken accordingly. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:47:58
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 13:47:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 13:47:38
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 13:47:38
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 13:47:38
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:07:03
User opened query 'Per MM: Please provide the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 18:46:35
User opened query 'PV Query: Please provide action taken with study drug. Per protocol, if a subject has a positive COVID-19 result prior to second vaccination dosing, study drug should be withdrawn. Please update action taken accordingly. ' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 16:57:10
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:12:40
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:04:31
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:04:34
User entered '1'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:04:35
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:32:00
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)	03 Nov 2020 21:12:16
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 'outcome resolution entered.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 20:47:43
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 20:46:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 20:46:59
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)	30 Oct 2020 01:01:10
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)	23 Oct 2020 21:22:20
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 'outcome not available yet.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 19:20:43
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:05:58
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 Sep 2020 16:56:37

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:06:01
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:31:29
User closed query 'PV Query: Please provide results for COVID saliva tests collected on 17 Sep, 19 Sep, 24 Sep, 01 Oct and 13 Oct.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 21:12:20
Query 'PV Query: Please provide results for COVID saliva tests collected on 17 Sep, 19 Sep, 24 Sep, 01 Oct and 13 Oct.' answered with 'as of 13 Oct, covid swab results are negative.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 20:46:45
User opened query 'PV Query: Please provide results for COVID saliva tests collected on 17 Sep, 19 Sep, 24 Sep, 01 Oct and 13 Oct.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 01:01:39
User closed query 'PV Query: Please provide results for COVID saliva tests collected on 17 Sep and 19 Sep, and any additional COVID testing with results and dates collected.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 21:22:11
Query 'PV Query: Please provide results for COVID saliva tests collected on 17 Sep and 19 Sep, and any additional COVID testing with results and dates collected.' answered with 'narrative updated for newest swab results' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 19:20:28
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:20:15
User entered 'PATIENT CAME IN FOR D29 VISIT BUT REPORTED SYMPTOMS BEGINNING 9/7/20 SO WAS CHANGED TO AN ILLNESS DAY 1 VISIT. PT ONLY EVER TREATED WITH MIDOL FOR SYMPTOMS BUT DID ADDITIONALLY EXPERIENCE HEADACHE WHICH SHE TOOK MOTRIN FOR AS WELL. Another COVID-19 swab test was done on 01 OCT 2020, in which the subject tested positive again.' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 19:20:15
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:20:35
User opened query 'PV Query: Please provide results for COVID saliva tests collected on 17 Sep and 19 Sep, and any additional COVID testing with results and dates collected.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 16:04:07
User closed query 'PV Query: Did the subject have any known exposure or risk factors for COVID-19?' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:08:00

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify COVID-19 testing. Please provide dates the tests were collected and dates tests resulted for swabs collected on 11 Sep, 13 Sep and 15 Sep. Additionally, please provide results from tests collected on 11 Sep and 15 Sep.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:07:57
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:07:54
Query 'PV Query: Please clarify COVID-19 testing. Please provide dates the tests were collected and dates tests resulted for swabs collected on 11 Sep, 13 Sep and 15 Sep. Additionally, please provide results from tests collected on 11 Sep and 15 Sep.' answered with 'updated in EDC' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:49:43
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:49:09
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 14:49:03
User entered 'Patient came in for D29 visit but reported symptoms beginning 9/7/20 so was changed to an illness day 1 visit. Pt only ever treated with midol for symptoms but did additionally experience headache which she took motrin for as well.' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 14:49:03
Query 'PV Query: Did the subject have any known exposure or risk factors for COVID-19?' answered with 'no' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:48:17
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:07:00

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Did the subject have any known exposure or risk factors for COVID-19?' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 16:57:35
User opened query 'PV Query: Please clarify COVID-19 testing. Please provide dates the tests were collected and dates tests resulted for swabs collected on 11 Sep, 13 Sep and 15 Sep. Additionally, please provide results from tests collected on 11 Sep and 15 Sep.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 16:57:26
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 16:56:55
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 20:12:40

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Nov 2020 21:02:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Nov 2020 21:02:49
Data point term sent to Coder	System	15 Nov 2020 21:02:15
User entered 'Headache'	(b) (4), (b) (6) (b) (4)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '19 Aug 2020'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
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	15 Nov 2020 21:02:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 21:02:09
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	15 Nov 2020 21:01:43
User entered '18:33'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Nov 2020 21:02:09
User entered '19 Aug 2020 18:33'	System	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		24 Nov 2020 21:04:53
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	24 Nov 2020 21:04:53
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	24 Nov 2020 20:14:43
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 21:03:33
User entered 'None (NONE)'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	15 Nov 2020 21:03:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Nov 2020 21:03:47
Data point term sent to Coder	System	15 Nov 2020 21:03:16
User entered 'Fatigue'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered '19 Aug 2020'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
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	15 Nov 2020 21:03:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 21:03:21
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	15 Nov 2020 21:03:10
User entered '18:33'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Nov 2020 21:03:21
User entered '19 Aug 2020 18:33'	System	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Aug 2020'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	15 Nov 2020 21:03:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 21:03:21
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	15 Nov 2020 21:03:10
User entered '18:55'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Nov 2020 21:03:21
User entered '23 Aug 2020 18:55'	System	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		24 Nov 2020 21:04:53
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	24 Nov 2020 21:04:53
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	24 Nov 2020 20:14:43
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[None](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:09:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Nov 2020 21:03:10

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:09:54

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please add Medication, dates and dosing for AE COVID 19, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 13:29:06
Query 'Per ETRTR: Please add Medication, dates and dosing for AE COVID 19, thanks.' answered with 'listed' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 14:53:08
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:07:21
User opened query 'Per ETRTR: Please add Medication, dates and dosing for AE COVID 19, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 17:40:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:34:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 09:52:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 09:52:13
Data point term sent to Coder	System	14 Aug 2020 15:35:41
User entered 'Multivitamin'	(b) (4), (b) (6)	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'chronic disease prophylaxis'	(b) (4), (b) (6)	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '1'	(b) (4), (b) (6)	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'capsule (CAPSULE)'	(b) (4), (b) (6)	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 21:16:42
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	14 Aug 2020 15:35:24
answered with 'conmed is still ongoing ' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 15:35:11
User entered 'un UNK 2017'	(b) (4), (b) (6)	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 15:35:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 15:37:22
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 Aug 2020 15:37:22
Data point term sent to Coder	System	14 Aug 2020 15:36:42
User entered 'Probiotic'	(b) (4), (b) (6)	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'chronic disease prophylaxis'	(b) (4), (b) (6)	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '1'	(b) (4), (b) (6)	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'capsule (CAPSULE)'	(b) (4), (b) (6)	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 21:16:47
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	14 Aug 2020 15:36:19
answered with 'conmed is still ongoing ' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 15:36:12
User entered 'un May 2020'	(b) (4), (b) (6)	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 15:36:12

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 18:52:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 18:52:39
Data point term sent to Coder	System	24 Sep 2020 18:52:02
User entered 'motrin'	(b) (4), (b) (6)	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM Re-Query: Please confirm if this SAR meets any AE reporting criteria. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 03:23:26
Query 'Per CDM Re-Query: Please confirm if this SAR meets any AE reporting criteria. Thank you' answered with 'confirmed that this did not meet criteria for reporting as AE due to resolving before day 7' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 15:00:23
User opened query 'Per CDM Re-Query: Please confirm if this SAR meets any AE reporting criteria. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 20:54:25
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 20:54:25
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'conmed recorded for solicited AE as reported in subject's eDiary' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:21:53

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 08:43:45
	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'headache'	(b) (4), (b) (6)	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '200'	(b) (4), (b) (6)	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'once daily (QD)'	(b) (4), (b) (6)	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '16 Aug 2020'	(b) (4), (b) (6)	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '16 Aug 2020'	(b) (4), (b) (6)	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Sep 2020 18:51:39

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 18:56:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 18:56:41
Data point term sent to Coder	System	24 Sep 2020 18:55:12
User entered 'motrin'	(b) (4), (b) (6)	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM Re-Query: Please confirm if this SAR meets any AE reporting criteria. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 03:24:19
Query 'Per CDM Re-Query: Please confirm if this SAR meets any AE reporting criteria. Thank you' answered with 'confirmed that this did not meet criteria for reporting as AE due to resolving before day 7' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 15:00:35
User opened query 'Per CDM Re-Query: Please confirm if this SAR meets any AE reporting criteria. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 20:54:56
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 20:54:56
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'conmed reported for solicited AE as reported in subject's eDiary' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:21:33

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 08:44:06
	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'headache'	(b) (4), (b) (6)	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '200'	(b) (4), (b) (6)	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'once daily (QD)'	(b) (4), (b) (6)	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '19 Aug 2020'	(b) (4), (b) (6)	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '19 Aug 2020'	(b) (4), (b) (6)	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Sep 2020 18:54:40

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MIDOL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 13:49:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 13:49:23
Data point term sent to Coder	System	09 Oct 2020 14:52:38
Coding entries removed.	(b) (4), (b) (6)	09 Oct 2020 14:52:34
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MIDOL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 06:06:51
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 Sep 2020 06:06:51
Data point term sent to Coder	System	24 Sep 2020 19:00:26
User entered 'midol'	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:27:09
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 14:52:34
User entered 'COVID' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 14:52:34
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'covid symptoms'	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '1'	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'capsule (CAPSULE)'	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'as needed (PRN)'	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '07 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 18:59:52

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 19:27:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 19:27:40
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	22 Oct 2020 19:26:58 22 Oct 2020 19:26:54
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 19:02:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 19:02:39
Data point term sent to Coder User entered 'ibuprofen'	System (b) (4), (b) (6)	24 Sep 2020 19:01:28 24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:27:32
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'indication updated' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 20:55:37
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:27:02
User entered 'Covid-19' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 19:26:54
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:41:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'headache'	(b) (4), (b) (6)	24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '600'	(b) (4), (b) (6)	24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'once (ONCE)'	(b) (4), (b) (6)	24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '13 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '13 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 19:01:11

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 19:28:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 19:28:41
Data point term sent to Coder	System	22 Oct 2020 19:27:59
Coding entries removed.	(b) (4), (b) (6)	22 Oct 2020 19:27:18
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 19:05:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 19:05:28
Data point term sent to Coder	System	24 Sep 2020 19:03:36
User entered 'IBUPROFEN'	(b) (4), (b) (6)	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:27:40
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'indication updated' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 20:55:46
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:27:18
User entered 'covid-19' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 19:27:18
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:41:48
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'headache'	(b) (4), (b) (6)	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '600'	(b) (4), (b) (6)	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'once (ONCE)'	(b) (4), (b) (6)	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '16 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered '16 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:10:38
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 19:02:44

US3672097

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:09:54

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:13:18
User entered '11 Sep 2020'	(b) (4), (b) (6)	30 Oct 2020 18:43:52

US3672097

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:09:54

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 21:04:53
Query 'Per CDM: please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 20:15:22
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:43
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:14:43
User opened query 'Per CDM: please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:31:07
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:13:20
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4), (b) (6)	30 Oct 2020 18:43:52

US3672097

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'AE#1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 21:04:53
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	24 Nov 2020 21:04:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 21:04:12
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	24 Nov 2020 21:04:05
User entered 'AE#1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 21:04:05
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	24 Nov 2020 20:17:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:17:03
Query 'Per CDM: Kindly remove all details and only provide the AE log line#. Thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 20:15:25
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	24 Nov 2020 20:14:43
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 20:14:43
User entered 'AE log line # 1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:14:43
User opened query 'Per CDM: Kindly remove all details and only provide the AE log line#. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 18:00:26
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:13:21

US3672097

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:09:54

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

Audit	User	Time (GMT)
User entered 'Positive covid-19 infection'	(b) (4), (b) (6)	30 Oct 2020 18:43:52

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'USA-US116-2020-MRNA-1273-P301000002'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'Cynthia'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'Strout'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered '1156 Bowman Road'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'Mount Pleasant'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:22:46
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:20:58
Un-reviewed for Safety.	System	12 Oct 2020 16:25:14
User entered empty.	System	12 Oct 2020 16:25:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 16:24:59
User entered 'SC'	(b) (4), (b) (6)	09 Oct 2020 13:37:17

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered '29464'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 16:24:59
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
User entered 'US'	System	20 Sep 2020 18:08:11

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 Nov 2020 23:31:24
User entered '3'	System	23 Oct 2020 21:23:01
User entered '2'	System	12 Oct 2020 16:25:14
User entered '1'	System	20 Sep 2020 18:08:11

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'USA-US116-2020-MRNA-1273-P301000002'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'Cynthia'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'Strout'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered '1156 Bowman Road'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'Mount Pleasant'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:22:46
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:20:58
Un-reviewed for Safety.	System	12 Oct 2020 16:25:14
User entered empty.	System	12 Oct 2020 16:25:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 16:24:59
User entered 'SC'	(b) (4), (b) (6)	09 Oct 2020 13:37:17

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered '29464'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 16:24:59
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
User entered 'US'	System	20 Sep 2020 18:08:11

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 Nov 2020 23:31:24
User entered '3'	System	23 Oct 2020 21:23:01
User entered '2'	System	12 Oct 2020 16:25:14
User entered '1'	System	20 Sep 2020 18:08:11

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:09:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
User entered '20/Sep/2020 14:08'	System	20 Sep 2020 18:08:11

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:09:54

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)	12 Oct 2020 16:24:59
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
User entered '1'	(b) (4), (b) (6)	20 Sep 2020 18:08:11

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'USA-US116-2020-MRNA-1273-P301000002'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'Cynthia'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'Strout'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered '1156 Bowman Road'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'Mount Pleasant'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:22:46
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:20:58
Un-reviewed for Safety.	System	12 Oct 2020 16:25:14
User entered empty.	System	12 Oct 2020 16:25:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 16:24:59
User entered 'SC'	(b) (4), (b) (6)	09 Oct 2020 13:37:17

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered '29464'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 16:24:59
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
User entered 'US'	System	20 Sep 2020 18:08:11

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 Nov 2020 23:31:24
User entered '3'	System	23 Oct 2020 21:23:01
User entered '2'	System	12 Oct 2020 16:25:14
User entered '1'	System	20 Sep 2020 18:08:11

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:09:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:21:10
User entered '12/Oct/2020 16:25'	System	12 Oct 2020 16:25:14

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:09:54

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)	23 Oct 2020 21:22:46
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:21:12
User entered '1'	(b) (4), (b) (6)	12 Oct 2020 16:25:14

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'USA-US116-2020-MRNA-1273-P301000002'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'Cynthia'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'Strout'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered '1156 Bowman Road'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'Mount Pleasant'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:22:46
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:20:58
Un-reviewed for Safety.	System	12 Oct 2020 16:25:14
User entered empty.	System	12 Oct 2020 16:25:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 16:24:59
User entered 'SC'	(b) (4), (b) (6)	09 Oct 2020 13:37:17

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered '29464'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 16:24:59
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
User entered 'US'	System	20 Sep 2020 18:08:11

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 Nov 2020 23:31:24
User entered '3'	System	23 Oct 2020 21:23:01
User entered '2'	System	12 Oct 2020 16:25:14
User entered '1'	System	20 Sep 2020 18:08:11

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:09:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:29:18
User entered '23/Oct/2020 17:23'	System	23 Oct 2020 21:23:01

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:09:54

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)	04 Nov 2020 13:29:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 23:31:06
User entered '1'	(b) (4), (b) (6)	23 Oct 2020 21:23:01

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'USA-US116-2020-MRNA-1273-P301000002'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'No (N)'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'Cynthia'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'Strout'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered '1156 Bowman Road'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered 'Mount Pleasant'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:22:46
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:20:58
Un-reviewed for Safety.	System	12 Oct 2020 16:25:14
User entered empty.	System	12 Oct 2020 16:25:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 16:24:59
User entered 'SC'	(b) (4), (b) (6)	09 Oct 2020 13:37:17

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:08:04
User entered '29464'	System	20 Sep 2020 18:07:18

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 16:24:59
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:11:10
User entered 'US'	System	20 Sep 2020 18:08:11

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 Nov 2020 23:31:24
User entered '3'	System	23 Oct 2020 21:23:01
User entered '2'	System	12 Oct 2020 16:25:14
User entered '1'	System	20 Sep 2020 18:08:11

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:09:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 13:29:26
User entered '03/Nov/2020 23:31'	System	03 Nov 2020 23:31:24

US3672097

Folder: SAE USA-US116-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:09:54

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)	04 Nov 2020 13:29:28
User entered '1'	(b) (4), (b) (6)	03 Nov 2020 23:31:24