

US3672097 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:54:27

All time stamps listed in this document are displayed in GMT

US3672097

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

[Participant ID](#)

US3672097

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

US3672097

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

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

US3672097

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

Date of Informed Consent (*dd MMM yyyy*) 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

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

Did the participant meet all eligibility criteria?

Yes

No

US3672097

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

Were any significant conditions reported?

Yes

No

US3672097

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3672097

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:51:52

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 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

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

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

US3672097

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

Height	ND - Not Done
Weight	ND - Not Done

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<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
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

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

US3672097

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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: 11 Aug 2021 22:54:27

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

TIMEPOINT

DAY 2

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

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: 11 Aug 2021 22:54:27

TIMEPOINT

DAY 3

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	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: 11 Aug 2021 22:54:27

TIMEPOINT

DAY 4

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

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: 11 Aug 2021 22:54:27

TIMEPOINT

DAY 5

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	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: 11 Aug 2021 22:54:27

TIMEPOINT

DAY 6

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

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: 11 Aug 2021 22:54:27

TIMEPOINT

DAY 7

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

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

	Yes <input type="checkbox"/>
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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

	Yes <input type="checkbox"/>
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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

	Yes <input type="checkbox"/>
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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

	Yes <input type="checkbox"/>
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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

TIMEPOINT

DAY 10

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

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: 11 Aug 2021 22:54:27

TIMEPOINT

DAY 11

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

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: 11 Aug 2021 22:54:27

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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: 11 Aug 2021 22:54:27

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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: 11 Aug 2021 22:54:27

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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: 11 Aug 2021 22:54:27

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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

Data signed: (b) (4) 15 Feb 2021 19:51:52

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:51:52

Generated On: 11 Aug 2021 22:54:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3672097

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:50:25

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:50:25

Generated On: 11 Aug 2021 22:54:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3672097

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:50:25

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:50:25

Generated On: 11 Aug 2021 22:54:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3672097

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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

US3672097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:27

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	_____
Time of assessment (<i>00:00-23:59</i>)	_____
Vital Signs Date and Time (derived)	_____
Temperature (<i>xxx.x</i>)	_____
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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: Physical Examination

Generated On: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) _____

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

Collection date and time (derived) _____

US3672097

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3672097

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:50:25

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:50:25

Generated On: 11 Aug 2021 22:54:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3672097

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:50:26

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:50:25

Generated On: 11 Aug 2021 22:54:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3672097

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:51:52

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:51:52

Generated On: 11 Aug 2021 22:54:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3672097

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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 <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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

Data signed: (b) (4) 16 Apr 2021 14:45:17

Generated On: 11 Aug 2021 22:54:27

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: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 13 OCT 2020

Collection time (*00:00-23:59*) 13:35 (24 HR)

Collection date and time (derived) 13 OCT 2020 13:35

US3672097

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:51:53

Generated On: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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: 11 Aug 2021 22:54:27

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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

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 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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

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 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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

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 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 DEC 2020 10:53:15
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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 21:45:24
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: 11 Aug 2021 22:54:27

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 13:02:42
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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

Date and time of submission

16 JAN 2021 11:08:53

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 13:18:35
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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 07:48:37
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: 11 Aug 2021 22:54:27

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 MAR 2021 13:15:36
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: 11 Aug 2021 22:54:27

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 MAR 2021 07:10:44
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: 11 Aug 2021 22:54:27

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 MAR 2021 17:44:19
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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 APR 2021 13:02:06
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: 11 Aug 2021 22:54:27

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 APR 2021 12:32:34
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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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
Patient Cloud Close Date & Time	15 JUN 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 11 Aug 2021 22:54:27

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°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: 11 Aug 2021 22:54:27

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

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:54:27

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 07:48:48

US3672097

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:53:38

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 05 Mar 2021 17:53:38

Generated On: 11 Aug 2021 22:54:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3672097

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:53:38

Generated On: 11 Aug 2021 22:54:27

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 1 DEC 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 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:53:38

Generated On: 11 Aug 2021 22:54:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3672097

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:53:38

Generated On: 11 Aug 2021 22:54:27

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 13 JAN 2021

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 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:53:38

Generated On: 11 Aug 2021 22:54:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3672097

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:53:38

Generated On: 11 Aug 2021 22:54:27

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 11 FEB 2021

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 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:53:38

Generated On: 11 Aug 2021 22:54:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3672097

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:45:17

Generated On: 11 Aug 2021 22:54:27

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 15 MAR 2021

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

Folder OID VISIT4

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:45:17

Generated On: 11 Aug 2021 22:54:27

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 _____

Height (derived) _____

Weight (derived) _____

US3672097

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:45:17

Generated On: 11 Aug 2021 22:54:27

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 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:45:17

Generated On: 11 Aug 2021 22:54:27

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 15 MAR 2021

Collection time (*00:00-23:59*) 10:19 (24 HR)

Collection date and time (derived) 15 MAR 2021 10:19

US3672097

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:45:17

Generated On: 11 Aug 2021 22:54:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3672097

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:45:17

Generated On: 11 Aug 2021 22:54:27

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 06 APR 2021

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 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:45:17

Generated On: 11 Aug 2021 22:54:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3672097

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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 <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	11 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.8 F
-------------	--------

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

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

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

309 of 2235

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Not Done

Fatigue None

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Nasal Congestion

- None
- Mild
- Moderate
- 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)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.3 F
-------------	--------

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

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

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Nasal Congestion

None

Mild

Moderate

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)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 13 SEP 2020

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 98.3 F

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Nasal Congestion

None

Mild

Moderate

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)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	14 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.2 F
-------------	--------

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

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

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Not Done

Fatigue None

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Nasal Congestion

None

Mild

Moderate

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)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	15 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	97.3 F
-------------	--------

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

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

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

325 of 2235

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Not Done

Fatigue

None

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Nasal Congestion

None

Mild

Moderate

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)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	16 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	98.3 F
-------------	--------

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

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

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Not Done

Fatigue None

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Nasal Congestion

None

Mild

Moderate

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)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	17 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	97.3 F
-------------	--------

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

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

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Not Done

Fatigue None

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Nasal Congestion

- None
- Mild
- Moderate
- 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)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	18 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	97.3 F
-------------	--------

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

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

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

337 of 2235

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Not Done

Fatigue None

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Nasal Congestion

- None
- Mild
- Moderate
- 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)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 19 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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Not Done

Fatigue None

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Nasal Congestion

None

Mild

Moderate

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)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	20 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	97.0 F
-------------	--------

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

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

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

345 of 2235

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Not Done

Fatigue None

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Nasal Congestion

- None
- Mild
- Moderate
- 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)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	21 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.0 F
-------------	--------

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

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

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

349 of 2235

EAB) (1725)

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Nasal Congestion

None

Mild

Moderate

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)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	22 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	95.2 F
-------------	--------

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

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

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

353 of 2235

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Not Done

Fatigue None

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Nasal Congestion

None

Mild

Moderate

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)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	23 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.6 F
-------------	--------

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

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

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

357 of 2235

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Not Done

Fatigue None

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Nasal Congestion

None

Mild

Moderate

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)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Symptom Day

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	24 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.6 F
-------------	--------

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

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

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

361 of 2235

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Not Done

Fatigue None

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

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Nasal Congestion

- None
- Mild
- Moderate
- 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

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

Did the subject have Respiratory Rates \geq 30 per Minute? Yes
No

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate \geq 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 _____

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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

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 _____

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

Hepatic Dysfunction? Yes
No

Start Date _____

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

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

[Generate Next COVID-19 Assessment](#)

Yes

No

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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 <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 05 Mar 2021 17:53:37

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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
Height (<i>xxx.x</i>)	163.8 cm
Weight (<i>xxx.x</i>)	97.6 kg
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:53:38

Generated On: 11 Aug 2021 22:54:27

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 01 FEB 2021

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

Folder OID UNBLND_DECIDE

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:45:17

Generated On: 11 Aug 2021 22:54:27

Date of updated informed consent (<i>dd MMM yyyy</i>)	01 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	01 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 17:53:38

Generated On: 11 Aug 2021 22:54:27

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 01 FEB 2021

Collection time (*00:00-23:59*) 09:07 (24 HR)

Collection date and time (derived) 01 FEB 2021 09:07

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 17:53:38

Generated On: 11 Aug 2021 22:54:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	01 FEB 2021
Collection time (<i>00:00 - 23:59</i>)	08:55
Collection Date and Time (derived)	01 FEB 2021 08:55

US3672097

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2235

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

Number of Days in ICU _____

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)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

AEID _____

Adverse event _____

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) _____

Start time (00:00-23:59) _____

AE start date and time (derived) _____

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) _____

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 _____

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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 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: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 AUG 2020
Start time (00:00-23:59)	18:33 (24 HR)
AE start date and time (derived)	14 AUG 2020 18:33
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

388 of 2235

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

391 of 2235

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

393 of 2235

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	UN MAY 2020
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

395 of 2235

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 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)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

397 of 2235

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 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)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

399 of 2235

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 07 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 13 OCT 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 (6)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

401 of 2235

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 13 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)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

403 of 2235

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 17:53:36

Generated On: 11 Aug 2021 22:54:27

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 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

Data signed: (b) (4) 08 Apr 2021 21:36:17

Generated On: 11 Aug 2021 22:54:27

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3672097

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 16 Apr 2021 14:45:17

Generated On: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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

Data signed: (b) (4) 05 Mar 2021 17:53:38

Generated On: 11 Aug 2021 22:54:27

SAEID	USA-US116-2020-MRNA-1273-P30 1000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 05 Mar 2021 17:53:38

Generated On: 11 Aug 2021 22:54:27

SAEID	USA-US116-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 05 Mar 2021 17:53:38

Generated On: 11 Aug 2021 22:54:27

SAEID	USA-US116-2020-MRNA-1273-P30 1000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 05 Mar 2021 17:53:38

Generated On: 11 Aug 2021 22:54:27

SAEID	USA-US116-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)

Data signed: (b) (4) 05 Mar 2021 17:53:38

Generated On: 11 Aug 2021 22:54:27

SAEID	USA-US116-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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: 11 Aug 2021 22:54:27

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
DataPoint Un-verified.	(b) (4) (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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
DataPoint Un-verified.	(b) (4) (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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
DataPoint Un-verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered 'SCRN'	System	13 Aug 2020 17:54:07

US3672097

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:27

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered (b) (6) 1981'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:49:28

US3672097

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:27

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '38'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:27

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered 'YEARS'	System	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:27

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered '38'	System	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:27

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:27

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:27

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '1'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:27

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:27

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:27

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:27

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:27

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:27

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:27

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:29:30

US3672097

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:27

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered 'Aug 2020'	System	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered '2020'	System	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:27

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Amendment 2 (2)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:27

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:27

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:27

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:54:45

US3672097

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:27

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:49:27

US3672097

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:27

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered '1'	System	13 Aug 2020 17:54:49

US3672097

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:54:49

US3672097

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:54:27

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
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: 11 Aug 2021 22:54:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '12:50'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered '13 Aug 2020 12:50'	System	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '165.4' cm	(b) (4) (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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '97.3' kg	(b) (4) (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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
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: 11 Aug 2021 22:54:27

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
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: 11 Aug 2021 22:54:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
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: 11 Aug 2021 22:54:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
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)	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: 11 Aug 2021 22:54:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
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: 11 Aug 2021 22:54:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered 'bpm'	System	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered 'breaths/min'	System	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered 'mmHg'	System	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered 'mmHg'	System	14 Aug 2020 15:30:11

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57

US3672097

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57

US3672097

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:20

US3672097

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:20

US3672097

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:54:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:38

US3672097

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	(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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	(b) (4)	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: 11 Aug 2021 22:54:27

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:38

US3672097

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:38

US3672097

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:54:27

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:38

US3672097

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:38

US3672097

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:54:27

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:38

US3672097

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:54:27

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:56

US3672097

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:54:27

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:56

US3672097

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:54:27

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:56

US3672097

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:54:27

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:56

US3672097

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:54:27

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
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) (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: 11 Aug 2021 22:54:27

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:56

US3672097

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:54:27

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:30:56

US3672097

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:54:27

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered empty.	System	14 Aug 2020 15:30:56

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'no risk identified'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '1'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '1'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '1'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'resident in a community with person to person transmisson'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:31:50

US3672097

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:54:18

US3672097

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:54:18

US3672097

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:54:18

US3672097

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User entered 'VISIT1'	System	13 Aug 2020 17:54:18

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 17:14:25

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) 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)	13 Aug 2020 17:14:25

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 17:14:25

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:54:29

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:54:29

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:54:29

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:27

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:54:29

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:27

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:54:29

US3672097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
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: 11 Aug 2021 22:54:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
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

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:27

Height

Audit	User	Time (GMT)
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). User entered '165.4' cm	(b) (4), (b) (6)	29 Aug 2020 04:30:37
	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	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: 11 Aug 2021 22:54:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
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

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:27

Height

Audit	User	Time (GMT)
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). User entered '165.4' cm	(b) (4), (b) (6)	29 Aug 2020 04:30:37
	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	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: 11 Aug 2021 22:54:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
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: 11 Aug 2021 22:54:27

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	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: 11 Aug 2021 22:54:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4)	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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '12:50' reason for change: Data Entry Error	(b) (4)	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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
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: 11 Aug 2021 22:54:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '98.6' F reason for change: Data Entry Error	(b) (4)	
	(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: 11 Aug 2021 22:54:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	(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: 11 Aug 2021 22:54:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '66' reason for change: Data Entry Error	(b) (4)	
	(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: 11 Aug 2021 22:54:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '16' reason for change: Data Entry Error	(b) (4)	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: 11 Aug 2021 22:54:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
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: 11 Aug 2021 22:54:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '113' reason for change: Data Entry Error	(b) (4)	
	(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: 11 Aug 2021 22:54:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
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: 11 Aug 2021 22:54:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '74' reason for change: Data Entry Error	(b) (4)	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: 11 Aug 2021 22:54:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
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: 11 Aug 2021 22:54:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
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

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:27

Height

Audit	User	Time (GMT)
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). User entered '165.4' cm	(b) (4), (b) (6)	29 Aug 2020 04:30:37
	(b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	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: 11 Aug 2021 22:54:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
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: 11 Aug 2021 22:54:27

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	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: 11 Aug 2021 22:54:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4)	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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
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)	
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)	17 Aug 2020 09:11:55
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).	(b) (4), (b) (6)	14 Aug 2020 15:33:29
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
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: 11 Aug 2021 22:54:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '98.8' F reason for change: Data Entry Error	(b) (4)	
	(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: 11 Aug 2021 22:54:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	(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: 11 Aug 2021 22:54:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:32:13

US3672097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '64' reason for change: Data Entry Error	(b) (4)	
	(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: 11 Aug 2021 22:54:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '16' reason for change: Data Entry Error	(b) (4)	
	(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: 11 Aug 2021 22:54:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
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: 11 Aug 2021 22:54:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '109' reason for change: Data Entry Error	(b) (4)	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: 11 Aug 2021 22:54:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
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: 11 Aug 2021 22:54:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '76' reason for change: Data Entry Error	(b) (4)	
	(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: 11 Aug 2021 22:54:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
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: 11 Aug 2021 22:54:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:33:36

US3672097

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:33:36

US3672097

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:54:27

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
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.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 21:06:06
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: 11 Aug 2021 22:54:27

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty; reason for change Data Entry Error	(b) (4)	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: 11 Aug 2021 22:54:27

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty; reason for change Data Entry Error	(b) (4)	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: 11 Aug 2021 22:54:27

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty; reason for change Data Entry Error	(b) (4)	
	(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: 11 Aug 2021 22:54:27

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
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: 11 Aug 2021 22:54:27

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:33:44

US3672097

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:54:27

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:33:44

US3672097

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:54:27

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User entered empty.	System	14 Aug 2020 15:33:44

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '13:35'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User entered '13 Aug 2020 13:35'	System	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User entered 'ONCE'	System	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 17:55:08

US3672097

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:34:03

US3672097

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:34:03

US3672097

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '13:15'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:34:03

US3672097

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
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: 11 Aug 2021 22:54:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:34:16

US3672097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:54:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
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: 11 Aug 2021 22:54:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:34:16

US3672097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:54:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '12:41'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:34:16

US3672097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
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: 11 Aug 2021 22:54:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
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: 11 Aug 2021 22:54:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:34:16

US3672097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:54:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 15:34:16

US3672097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User entered empty.	System	14 Aug 2020 15:34:16

US3672097

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User closed query 'Per CDM RQ: Response noted however, there are no data recorded in V2D29 folder, please review and record the data, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 05:08:02
Query 'Per CDM RQ: Response noted however, there are no data recorded in V2D29 folder, please review and record the data, else clarify.' answered with 'visit 2/day 29 not completed due to patient having an illness visit during that window' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 21:38:26
User opened query 'Per CDM RQ: Response noted however, there are no data recorded in V2D29 folder, please review and record the data, else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 11:04:33
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: 11 Aug 2021 22:54:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User entered '1'	System	14 Aug 2020 15:34:20

US3672097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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).	(b) (4), (b) (6)	09 Oct 2020 17:53:10
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: 11 Aug 2021 22:54:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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).	(b) (4), (b) (6)	21 Oct 2020 17:58:20
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: 11 Aug 2021 22:54:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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 System prevents daily activity (3)'		16 Aug 2020 22:35:16

US3672097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:05:14

US3672097

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:05:14

US3672097

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:05:14

US3672097

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:05:14

US3672097

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:05:18

US3672097

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User entered '1'	System	21 Aug 2020 18:05:18

US3672097

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 17:13:45

US3672097

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
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.' answered with 'added pd due to subject being oow' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 17:13:53
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 17:13:45

US3672097

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 17:13:45

US3672097

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 17:13:57

US3672097

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:18:30
User entered '1'	System	31 Aug 2020 17:13:57

US3672097

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:05
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:19:24

US3672097

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:05
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:19:24

US3672097

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:05
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:19:24

US3672097

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:05
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:19:24

US3672097

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:05
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:19:28

US3672097

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:29:05
User entered '1'	System	03 Sep 2020 19:19:28

US3672097

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
Query 'Per CDM: Was this visit performed? = No, however, Continuing page = Yes. Please update or clarify accordingly.' canceled (Site from DM).	(b) (4) (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: 11 Aug 2021 22:54:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:36:58

US3672097

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:36:58

US3672097

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered 'VISIT2'	System	23 Sep 2020 14:36:58

US3672097

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:37:04

US3672097

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered '1'	System	23 Sep 2020 14:37:04

US3672097

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 13:13:47

US3672097

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 13:13:47

US3672097

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 13:13:47

US3672097

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
User entered 'on illness track'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 13:13:47

US3672097

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:50:26
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: 11 Aug 2021 22:54:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User entered '1'	System	13 Oct 2020 19:29:00

US3672097

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 13:13:53

US3672097

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 13:13:53

US3672097

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 13:13:53

US3672097

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:50:26
User entered 'on illness track'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 13:13:53

US3672097

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:50:26
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: 11 Aug 2021 22:54:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User entered '1'	System	13 Oct 2020 19:29:09

US3672097

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 13:13:04

US3672097

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 13:13:04

US3672097

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 13:13:04

US3672097

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'on illness track'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 13:13:04

US3672097

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
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: 11 Aug 2021 22:54:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User entered '1'	System	13 Oct 2020 19:29:18

US3672097

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
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: 11 Aug 2021 22:54:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
User entered '13 Oct 2020'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:29:29

US3672097

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
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: 11 Aug 2021 22:54:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User entered 'VISIT3'	System	13 Oct 2020 19:29:29

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
User entered '13:10'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
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: 11 Aug 2021 22:54:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
User entered '98.1' F	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
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: 11 Aug 2021 22:54:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
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: 11 Aug 2021 22:54:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
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: 11 Aug 2021 22:54:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User entered 'bpm'	System	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
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: 11 Aug 2021 22:54:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User entered 'breaths/min'	System	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
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: 11 Aug 2021 22:54:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User entered 'mmHg'	System	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
User entered '79'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User entered 'mmHg'	System	13 Oct 2020 19:30:31

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36

US3672097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36

US3672097

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User closed query 'Per CDM: Visit 3 Day 57 and Convalescence Visit Day 28 are both dated 13 Oct 2020. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 08:16:06
Query 'Per CDM: Visit 3 Day 57 and Convalescence Visit Day 28 are both dated 13 Oct 2020. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 17:27:27
Signature has been broken.	(b) (4), (b) (6)	25 Mar 2021 17:27:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 17:27:22
User opened query 'Per CDM: Visit 3 Day 57 and Convalescence Visit Day 28 are both dated 13 Oct 2020. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 18:55:30
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered 'No (N)'	Patty Howenstine (b) (4)	13 Oct 2020 19:30:34

US3672097

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:27:22
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 17:27:22
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:51:53
User entered empty.	(b) (4) Patty Howenstine (b) (4)	13 Oct 2020 19:30:34

US3672097

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
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: 11 Aug 2021 22:54:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
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: 11 Aug 2021 22:54:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:51:53
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: 11 Aug 2021 22:54:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:43:36
User entered '1'	System	13 Oct 2020 19:30:03

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 71'	System	13 Aug 2020 17:55:08

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[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)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46
Data entry locked.	System	13 Aug 2020 17:55:08
User entered '20 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: 11 Aug 2021 22:54:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46
Data entry locked.	System	13 Aug 2020 17:55:08
User entered '24 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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 78'	System	13 Aug 2020 17:55:08

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[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)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46
Data entry locked.	System	13 Aug 2020 17:55:08
User entered '27 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: 11 Aug 2021 22:54:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46
Data entry locked.	System	13 Aug 2020 17:55:08
User entered '31 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: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: 11 Aug 2021 22:54:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:16:16
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: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46
Data entry locked.	System	13 Aug 2020 17:55:08
User entered 'Day 99'	System	13 Aug 2020 17:55:08

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[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)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46

US3672097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46
Data entry locked.	System	13 Aug 2020 17:55:08
User entered '17 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: 11 Aug 2021 22:54:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:16:46
Data entry locked.	System	13 Aug 2020 17:55:08
User entered '21 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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: '2020-12-22T10:53:02', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '9e536518-8a17-4a35-b5f2-4dd8f14b23b5'	System	22 Dec 2020 15:53:24
User entered 'No (N)'	System	22 Dec 2020 15:53:24

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you been exposed to someone with 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: '2020-12-22T10:53:07', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '9e536518-8a17-4a35-b5f2-4dd8f14b23b5'	System	22 Dec 2020 15:53:24
User entered 'Yes (Y)'	System	22 Dec 2020 15:53:24

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-12-22T10:53:11', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '9e536518-8a17-4a35-b5f2-4dd8f14b23b5'	System	22 Dec 2020 15:53:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Dec 2020 15:53:24

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2020-12-22T10:53:15', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '9e536518-8a17-4a35-b5f2-4dd8f14b23b5'	System	22 Dec 2020 15:53:24
User entered '22 Dec 2020 10:53:15'	System	22 Dec 2020 15:53:24

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: '2021-01-03T21:45:17', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'b060e42c-8ca8-4695-a757-3cd0337a6920'	System	04 Jan 2021 02:45:28
User entered 'No (N)'	System	04 Jan 2021 02:45:28

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you been exposed to someone with 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: '2021-01-03T21:45:20', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'b060e42c-8ca8-4695-a757-3cd0337a6920'	System	04 Jan 2021 02:45:28
User entered 'No (N)'	System	04 Jan 2021 02:45:28

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2021-01-03T21:45:24', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'b060e42c-8ca8-4695-a757-3cd0337a6920'	System	04 Jan 2021 02:45:28
User entered '03 Jan 2021 21:45:24'	System	04 Jan 2021 02:45:28

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: '2021-01-09T13:02:31', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'c307d8b1-c64d-441e-8cbc-2218a98ce69a'	System	09 Jan 2021 18:02:46
User entered 'No (N)'	System	09 Jan 2021 18:02:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you been exposed to someone with 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: '2021-01-09T13:02:37', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'c307d8b1-c64d-441e-8cbc-2218a98ce69a'	System	09 Jan 2021 18:02:46
User entered 'No (N)'	System	09 Jan 2021 18:02:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2021-01-09T13:02:42', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'c307d8b1-c64d-441e-8cbc-2218a98ce69a' User entered '09 Jan 2021 13:02:42'	System	09 Jan 2021 18:02:46
	System	09 Jan 2021 18:02:46

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: '2021-01-16T11:08:43', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'Ifad8bd9-876f-440f-8ba4-8583cddad948'	System	16 Jan 2021 16:08:56
User entered 'No (N)'	System	16 Jan 2021 16:08:56

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you been exposed to someone with 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: '2021-01-16T11:08:48', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '1fad8bd9-876f-440f-8ba4-8583cddad948'	System	16 Jan 2021 16:08:56
User entered 'No (N)'	System	16 Jan 2021 16:08:56

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2021-01-16T11:08:53', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'Ifad8bd9-876f-440f-8ba4-8583cddad948'	System	16 Jan 2021 16:08:56
User entered '16 Jan 2021 11:08:53'	System	16 Jan 2021 16:08:56

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: '2021-02-15T13:18:26', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '2caf60b0-b330-42ac-8ff7-33ac479151d6'	System	15 Feb 2021 18:18:39
User entered 'No (N)'	System	15 Feb 2021 18:18:39

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you been exposed to someone with 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: '2021-02-15T13:18:30', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '2caf60b0-b330-42ac-8ff7-33ac479151d6'	System	15 Feb 2021 18:18:39
User entered 'No (N)'	System	15 Feb 2021 18:18:39

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2021-02-15T13:18:35', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '2caf60b0-b330-42ac-8ff7-33ac479151d6'	System	15 Feb 2021 18:18:39
User entered '15 Feb 2021 13:18:35'	System	15 Feb 2021 18:18:39

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: '2021-03-03T07:48:29', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '14d20e75-f3e5-452e-96ea-5b27d94b029b'	System	03 Mar 2021 12:48:44
User entered 'No (N)'	System	03 Mar 2021 12:48:44

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you been exposed to someone with 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: '2021-03-03T07:48:34', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '14d20e75-f3e5-452e-96ea-5b27d94b029b'	System	03 Mar 2021 12:48:44
User entered 'No (N)'	System	03 Mar 2021 12:48:44

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2021-03-03T07:48:37', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '14d20e75-f3e5-452e-96ea-5b27d94b029b'	System	03 Mar 2021 12:48:44
User entered '03 Mar 2021 07:48:37'	System	03 Mar 2021 12:48:44

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: '2021-03-10T13:15:26', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '0fee94a4-3f9c-4a53-9c63-82ac1ccc1934'	System	10 Mar 2021 18:17:10
User entered 'No (N)'	System	10 Mar 2021 18:17:10

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you been exposed to someone with 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: '2021-03-10T13:15:29', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '0fee94a4-3f9c-4a53-9c63-82ac1ccc1934'	System	10 Mar 2021 18:17:10
User entered 'No (N)'	System	10 Mar 2021 18:17:10

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2021-03-10T13:15:36', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '0fee94a4-3f9c-4a53-9c63-82ac1ccc1934'	System	10 Mar 2021 18:17:10
User entered '10 Mar 2021 13:15:36'	System	10 Mar 2021 18:17:10

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: '2021-03-15T07:10:37', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '1e2a73ad-5ce9-4ad8-b1cd-9563476c36f9'	System	15 Mar 2021 11:10:48
User entered 'No (N)'	System	15 Mar 2021 11:10:48

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you been exposed to someone with 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: '2021-03-15T07:10:41', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '1e2a73ad-5ce9-4ad8-b1cd-9563476c36f9'	System	15 Mar 2021 11:10:48
User entered 'No (N)'	System	15 Mar 2021 11:10:48

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2021-03-15T07:10:44', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '1e2a73ad-5ce9-4ad8-b1cd-9563476c36f9'	System	15 Mar 2021 11:10:48
User entered '15 Mar 2021 07:10:44'	System	15 Mar 2021 11:10:48

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: '2021-03-23T17:44:12', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '367d25e7-8033-454b-ba40-da69bf84fbf0'	System	23 Mar 2021 21:44:22
User entered 'No (N)'	System	23 Mar 2021 21:44:22

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you been exposed to someone with 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: '2021-03-23T17:44:15', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '367d25e7-8033-454b-ba40-da69bf84fbf0'	System	23 Mar 2021 21:44:22
User entered 'No (N)'	System	23 Mar 2021 21:44:22

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2021-03-23T17:44:19', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '367d25e7-8033-454b-ba40-da69bf84fbf0' User entered '23 Mar 2021 17:44:19'	System	23 Mar 2021 21:44:22
	System	23 Mar 2021 21:44:22

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: '2021-04-18T13:01:55', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '25d82552-de9e-4db8-b203-5af4dc99e482'	System	18 Apr 2021 17:04:13
User entered 'No (N)'	System	18 Apr 2021 17:04:13

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you been exposed to someone with 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: '2021-04-18T13:01:57', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '25d82552-de9e-4db8-b203-5af4dc99e482'	System	18 Apr 2021 17:04:13
User entered 'No (N)'	System	18 Apr 2021 17:04:13

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2021-04-18T13:02:06', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: '25d82552-de9e-4db8-b203-5af4dc99e482'	System	18 Apr 2021 17:04:13
User entered '18 Apr 2021 13:02:06'	System	18 Apr 2021 17:04:13

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: '2021-04-28T12:32:27', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'e5a26c9c-2110-4025-837c-83f14dcaed95'	System	28 Apr 2021 23:43:53
User entered 'No (N)'	System	28 Apr 2021 23:43:53

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

Have you been exposed to someone with 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: '2021-04-28T12:32:32', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'e5a26c9c-2110-4025-837c-83f14dcaed95'	System	28 Apr 2021 23:43:53
User entered 'No (N)'	System	28 Apr 2021 23:43:53

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2021-04-28T12:32:34', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'e5a26c9c-2110-4025-837c-83f14dcaed95'	System	28 Apr 2021 23:43:53
User entered '28 Apr 2021 12:32:34'	System	28 Apr 2021 23:43:53

US3672097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:54:27

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2021-03-03T07:48:44', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'e3e88df6-3b95-4831-b027-f57efdfd5c6d'	System	03 Mar 2021 12:48:52
User entered 'No (N)'	System	03 Mar 2021 12:48:52

US3672097

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:54:27

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10f568eccf40e085)', Time: '2021-03-03T07:48:48', User OID: 'PatientReportedOutcome (US3672097)', ODM File OID: 'e3e88df6-3b95-4831-b027-f57efdfd5c6d'	System	03 Mar 2021 12:48:52
User entered '03 Mar 2021 07:48:48'	System	03 Mar 2021 12:48:52

US3672097

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:32:06
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:42:38

US3672097

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:32:06
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered '9 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:42:38

US3672097

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:32:06
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:42:38

US3672097

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:32:06
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:42:38

US3672097

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:32:06
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:42:43

US3672097

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:32:06
User entered '1'	System	10 Nov 2020 14:42:43

US3672097

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:34:18

US3672097

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered '1 Dec 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:34:18

US3672097

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:34:18

US3672097

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:34:18

US3672097

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:34:33

US3672097

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User entered '1'	System	02 Dec 2020 16:34:33

US3672097

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:15:30

US3672097

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:15:30

US3672097

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:15:30

US3672097

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:15:30

US3672097

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:15:33

US3672097

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User entered '1'	System	13 Jan 2021 17:15:33

US3672097

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:53:48

US3672097

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:53:48

US3672097

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:53:48

US3672097

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:53:48

US3672097

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:53:52

US3672097

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:07:23
User entered '1'	System	16 Feb 2021 17:53:52

US3672097

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 14:29:18

US3672097

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered '15 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 14:29:18

US3672097

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Mar 2021 14:29:18

US3672097

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User entered 'VISIT4'	System	15 Mar 2021 14:29:18

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 17:51:46

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 17:51:46

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 17:51:46

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User entered empty.	System	31 Mar 2021 17:51:46

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 17:51:46

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 17:51:46

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 17:51:46

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 17:51:46

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User entered empty.	System	31 Mar 2021 17:51:46

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 17:51:46

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User entered empty.	System	31 Mar 2021 17:51:46

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 17:51:46

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User entered empty.	System	31 Mar 2021 17:51:46

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 17:51:46

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User entered empty.	System	31 Mar 2021 17:51:46

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45

US3672097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45

US3672097

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered 'No (N)'	(b) (4), (b) (6)	15 Mar 2021 14:29:23

US3672097

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 14:29:23

US3672097

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 15:10:37

US3672097

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered '15 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 15:10:37

US3672097

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered '10:19'	(b) (4), (b) (6)	15 Mar 2021 15:10:37

US3672097

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User entered '15 Mar 2021 10:19'	System	15 Mar 2021 15:10:37

US3672097

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 14:29:34

US3672097

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:45
User entered '1'	System	15 Mar 2021 14:29:34

US3672097

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:52:23

US3672097

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:52:23

US3672097

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:52:23

US3672097

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:52:23

US3672097

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:52:14

US3672097

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:27

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 17:52:14

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:54:27

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:39:50
User entered '11 Sep 2020'	Patty Howenstine (b) (4) (b) (4)	15 Sep 2020 14:19:16

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:54:27

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:39:50
User entered '12:30'	Patty Howenstine (b) (4) (b) (4)	15 Sep 2020 14:19:16

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:54:27

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:09
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: 11 Aug 2021 22:54:27

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:39:50
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Patty Howenstine (b) (4) (b) (4)	15 Sep 2020 14:19:16

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:54:27

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:39:50
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	15 Sep 2020 14:19:16

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:53:39
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: 11 Aug 2021 22:54:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
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)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:46:23
User entered '0'	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: 11 Aug 2021 22:54:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:46:23
User entered '99'	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: 11 Aug 2021 22:54:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User entered '%'	System	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
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)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:46:23
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: 11 Aug 2021 22:54:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	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)	15 Sep 2020 14:22:48
	(b) (4)	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:46:23
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: 11 Aug 2021 22:54:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:46:23
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: 11 Aug 2021 22:54:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	
	(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)	15 Sep 2020 14:22:48
	(b) (4)	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:46:23
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: 11 Aug 2021 22:54:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:46:23
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: 11 Aug 2021 22:54:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
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)	15 Sep 2020 14:22:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:46:23
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: 11 Aug 2021 22:54:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:46:23
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: 11 Aug 2021 22:54:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
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)	15 Sep 2020 14:22:48
	(b) (4)	

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:46:23
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: 11 Aug 2021 22:54:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:46:23
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: 11 Aug 2021 22:54:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:46:23
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: 11 Aug 2021 22:54:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:46:23
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: 11 Aug 2021 22:54:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:46:23
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 (2)

Generated On: 11 Aug 2021 22:54:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User entered '%'	System	21 Oct 2020 16:25:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User entered '%'	System	21 Oct 2020 16:26:41

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Day 4 (Day 4)'	(b) (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: 11 Aug 2021 22:54:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User entered '%'	System	21 Oct 2020 16:27:46

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User entered '%'	System	21 Oct 2020 16:28:31

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User entered '%'	System	21 Oct 2020 16:29:21

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User entered '%'	System	21 Oct 2020 16:30:04

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User entered '%'	System	21 Oct 2020 16:30:48

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User entered '%'	System	21 Oct 2020 16:31:43

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User entered '%'	System	21 Oct 2020 16:32:25

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User entered '%'	System	21 Oct 2020 16:33:32

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User entered '%'	System	21 Oct 2020 16:34:11

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User entered '%'	System	21 Oct 2020 16:34:44

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Day 14 (Day 14)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
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: 11 Aug 2021 22:54:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User entered '%'	System	21 Oct 2020 16:35:20

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:48:55
User entered '11 Sep 2020'	Patty Howenstine (b) (4) (b) (4)	15 Sep 2020 14:23:56

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:27

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:48:55
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	15 Sep 2020 14:23:56

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:27

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 17:41:12
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 12:48:55
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: 11 Aug 2021 22:54:27

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:48:55
User entered '11 Sep 2020'	Patty Howenstine (b) (4) (b) (4)	15 Sep 2020 14:23:56

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:27

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:48:55
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Patty Howenstine (b) (4) (b) (4)	15 Sep 2020 14:23:56

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:27

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:48:55
User entered empty.	Patty Howenstine (b) (4) (b) (4)	15 Sep 2020 14:23:56

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:27

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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)'	(b) (4) Patty Howenstine (b) (4)	15 Sep 2020 14:23:56

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:27

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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'	(b) (4) Patty Howenstine (b) (4)	15 Sep 2020 14:23:56

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:27

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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)'	(b) (4) Patty Howenstine (b) (4)	15 Sep 2020 14:23:56

US3672097

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:27

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:32
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: 11 Aug 2021 22:54:27

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:42:34
User closed query 'Please complete this page per source. Thanks' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 15:26:41
Query 'Please complete this page per source. Thanks' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 15:26:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 17:46:34
User opened query 'Please complete this page per source. Thanks' (Site from CRA).	(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)	09 Oct 2020 12:50:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 13:24:00
User entered empty.	System	01 Oct 2020 13:23:43
	(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: 11 Aug 2021 22:54:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	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: 11 Aug 2021 22:54:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	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: 11 Aug 2021 22:54:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:25:39
User closed query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and provide responses. (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 08:56:25
Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and provide responses. answered with 'no evidence at visit' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 22:22:54
DataPoint Un-verified.	(b) (4), (b) (6)	11 Jan 2021 22:22:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 22:22:39
User opened query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and provide responses. (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 04:32:57
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: 11 Aug 2021 22:54:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Evidence of Shock Requires Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:41
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:31:52
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 12:51:42
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	15 Sep 2020 13:37:56

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:54:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
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: 11 Aug 2021 22:54:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User closed 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) (4), (b) (6)	18 Dec 2020 05:11:20
Query 'Per GCL Lab Recon: Re-query: Saliva: Response noted, however please confirm the sample collection date for Day 3. Thank you.' answered with 'confirm' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:25:45
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

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:54:27

[Date of Collection](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 09:50:08
	(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: 11 Aug 2021 22:54:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
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: 11 Aug 2021 22:54:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
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: 11 Aug 2021 22:54:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
User closed query 'Per GCL Lab Recon: Saliva: Re-query: Thanks for your response, please confirm the correct date for Day 7.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 06:59:40
Query 'Per GCL Lab Recon: Saliva: Re-query: Thanks for your response, please confirm the correct date for Day 7.' answered with 'Date is correct, we do not have access to PPD corrections' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 17:35:09
User opened query 'Per GCL Lab Recon: Saliva: Re-query: Thanks for your response, please confirm the correct date for Day 7.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 07:52:56
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 17SEP2020 for Day 7 is recorded in EDC, however sample is reported with 24Sep2020 for Day 7 with Accession # 1F652623576 in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal to reflect correct. thank you.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 07:52:56
Query 'Per GCL Lab Recon: Saliva: Sample dated 17SEP2020 for Day 7 is recorded in EDC, however sample is reported with 24Sep2020 for Day 7 with Accession # 1F652623576 in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal to reflect correct. thank you.' answered with 'Accession Number: 1F67355' (Site from DM).	Patty Howenstine (b) (4) (b) (4)	23 Mar 2021 14:06:24
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 17SEP2020 for Day 7 is recorded in EDC, however sample is reported with 24Sep2020 for Day 7 with Accession # 1F652623576 in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal to reflect correct. thank you.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 07:08:11
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:53:39

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:54:27

Date of Collection

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, sample still not received please provide the tracking number and shipping date in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 06:51:40
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, sample still not received please provide the tracking number and shipping date in query response for tracking purpose.' answered with 'Accession Number: 1F67355' (Site from DM).	Patty Howenstine (b) (4) (b) (4)	15 Feb 2021 16:13:26
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, sample still not received please provide the tracking number and shipping date in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 05:41:24
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 05:41:24
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose.' answered with 'Accession number: 1F67355' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 21:30:04
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 06:16:16
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Response noted, however if the sample dated 17SEP2020 has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 06:16:16
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Response noted, however if the sample dated 17SEP2020 has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'accession # 1F67355' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 22:27:03

US3672097

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:54:27

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Response noted, however if the sample dated 17SEP2020 has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 08:12:27
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17SEP2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 05:11:34
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17SEP2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'confirm' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:26:19
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17SEP2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:06:49
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: 11 Aug 2021 22:54:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
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: 11 Aug 2021 22:54:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
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: 11 Aug 2021 22:54:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
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: 11 Aug 2021 22:54:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
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: 11 Aug 2021 22:54:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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) (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: 11 Aug 2021 22:54:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
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).	(b) (4), (b) (6)	17 Nov 2020 09:48:42
DataPoint Verified.	(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) (6)	08 Oct 2020 20:32:09

US3672097

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:16
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:16
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:16
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:16
User entered 'SICKD1'	System	08 Oct 2020 20:20:52

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25
User entered 'bpm'	System	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25
User entered 'breaths/min'	System	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25
User entered 'mmHg'	System	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25
User entered 'mmHg'	System	08 Oct 2020 20:28:46

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25

US3672097

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:25

US3672097

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:38:34
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:23:26

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:38:34
User entered '13 Oct 2020'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:23:26

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:38:34
User entered 'Clinic (Clinic)'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:23:26

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User entered 'SICKD28'	System	13 Oct 2020 19:23:26

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered '13 Oct 2020'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered '13:10'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered '98.1' F	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered 'Oral (Oral)'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered empty.	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered '68'	Patty Howenstine (b) (4)	13 Oct 2020 19:27:54
	(b) (4)	

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User entered 'bpm'	System	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered '15'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User entered 'breaths/min'	System	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered '124'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User entered 'mmHg'	System	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:40:43
User entered '79'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User entered 'mmHg'	System	13 Oct 2020 19:27:54

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:40:59
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:28:03

US3672097

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:40:59
User entered '13 Oct 2020'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:28:03

US3672097

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:54:27

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:41:09
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (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: 11 Aug 2021 22:54:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:39:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:41:09
User entered '13 Oct 2020'	Patty Howenstine (b) (4) (b) (4)	13 Oct 2020 19:28:08

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:00:02

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:00:02

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:00:02

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 15:00:02

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:27

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:00:16

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:27

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:17:23
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:51:56

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:27

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:00:16

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:27

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User closed query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 09:36:22
Query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:17:49
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 13:17:23
User opened query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 07:58:04
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:51:56

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:27

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:00:16

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:27

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:00:16

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:27

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:00:16

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:27

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Not Administered (NA)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:00:16

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:27

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:00:16

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:27

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered '1'	System	01 Feb 2021 15:00:16

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:54:27

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered empty.	System	01 Feb 2021 15:00:16

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:02:09

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:02:09

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered '09:07'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:02:09

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered '01 Feb 2021 09:07'	System	01 Feb 2021 15:02:09

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:54:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:00:44

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:54:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:00:44

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:54:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User entered '08:55'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:00:44

US3672097

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:13:57
User entered '01 Feb 2021 08:55'	System	01 Feb 2021 15:00:44

US3672097

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:54:27

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:56:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	
	(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	System	20 Sep 2020 18:07:18
'USA-US116-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	20 Sep 2020 18:07:18

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:27

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	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, HLG: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (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)	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, HLG: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (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)	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: 11 Aug 2021 22:54:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
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: 11 Aug 2021 22:54:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 22:54:27

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	20 Oct 2020 15:20:23
	(b) (4), (b) (6)	
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: 11 Aug 2021 22:54:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	20 Oct 2020 15:20:21
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:27

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	25 Nov 2020 16:25:38
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. answered with 'dosing discontinuation completed' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:45:06
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

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:27

Action taken with investigational product

Audit	User	Time (GMT)
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
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

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:27

Action taken with investigational product

Audit	User	Time (GMT)
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: 11 Aug 2021 22:54:27

None

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:27

[Outcome](#)

Audit	User	Time (GMT)
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
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: 11 Aug 2021 22:54:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	04 Nov 2020 13:31:29
	(b) (4), (b) (6)	
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

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:27

[Narrative](#)

Audit	User	Time (GMT)
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
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

US3672097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:27

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 13:07:00
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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User closed query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4. Please review and update to delete/remove AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 04:38:56
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 04:38:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 03:42:28
Data point term sent to Coder	System	17 Dec 2020 13:15:39
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 13:15:06
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'deleted' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:14:57
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 13:14:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:14:47
Query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4. Please review and update to delete/remove AE as applicable. Otherwise, clarify.' answered with 'will delete' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:14:08
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 12:19:12

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4. Please review and update to delete/remove AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 03:44:53
User coded data point as SOC: Nervous system disorders, HLT: 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)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	23 Feb 2021 19:27:04
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 03:42:35
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 13:15:12
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 13:14:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:14:47
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 03:42:37
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 13:15:15
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 13:14:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:14:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	23 Feb 2021 19:27:04
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 03:42:40
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 13:15:17
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 13:14:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:14:47
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	23 Feb 2021 19:27:04
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 03:42:42
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 13:15:20
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 13:14:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:14:47
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: 11 Aug 2021 22:54:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	23 Feb 2021 19:27:04
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 03:42:44
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 13:15:22
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 13:14:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:14:47
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:14:47
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: 11 Aug 2021 22:54:27

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	23 Feb 2021 19:27:04
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 03:42:47
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 13:15:25
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 13:14:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:14:47
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: 11 Aug 2021 22:54:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 03:42:48
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 13:15:27
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 13:14:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:14:47
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

Death

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 03:42:52
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 13:15:30
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 13:14:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:14:47
User entered 'Related (RELATED)'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	23 Feb 2021 19:27:04
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 03:42:54
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 13:15:33
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 13:14:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:14:47
User entered 'Related (RELATED)'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
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)	18 Dec 2020 04:39:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 03:42:57
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 13:15:37
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' answered with 'added in error' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:15:35
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 13:14:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:14:47
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)	05 Dec 2020 03:44:43
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

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
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: 11 Aug 2021 22:54:27

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
Query 'Other action taken is missing. Please check at least one action from the options provided.' canceled (Site from System).	(b) (4), (b) (6)	18 Dec 2020 07:15:42
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	17 Dec 2020 13:14:47
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:14:47
User entered '1'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	23 Feb 2021 19:27:04
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 03:43:01
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 13:15:40
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 13:14:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:14:47
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: 11 Aug 2021 22:54:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:01:43

US3672097

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

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: 11 Aug 2021 22:54:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 04:38:17
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'confirm' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:16:10
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 12:19:20
User coded data point as SOC: General disorders and administration site conditions, HLG: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\23.0.	Coder Import (b) (4) (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) (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: 11 Aug 2021 22:54:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:27:04
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 14AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 15:59:34
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 14AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:16:56
User entered '14 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:16:30
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 14AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 03:45:13
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: 11 Aug 2021 22:54:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User closed query 'Per CDM: Kindly try to provide the estimated time the AE started if known. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 04:30:19
Query 'Per CDM: Kindly try to provide the estimated time the AE started if known. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 22:17:48
User entered '18:33' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 22:17:42
User opened query 'Per CDM: Kindly try to provide the estimated time the AE started if known. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 04:38:52
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 04:37:43
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 13:17:05
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Dec 2020 13:16:30
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: 11 Aug 2021 22:54:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User entered '14 Aug 2020 18:33'	System	11 Jan 2021 22:17:42
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: 11 Aug 2021 22:54:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
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: 11 Aug 2021 22:54:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:27:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 04:36:51
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 13:17:09
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Dec 2020 13:16:30
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: 11 Aug 2021 22:54:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
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: 11 Aug 2021 22:54:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
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: 11 Aug 2021 22:54:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered 'Related (RELATED)'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered 'Related (RELATED)'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
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)	18 Dec 2020 16:01:56
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:18:39
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:18:31
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)	05 Dec 2020 03:45:04
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

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

Action taken with investigational product

Audit	User	Time (GMT)
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: 11 Aug 2021 22:54:27

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered '1'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
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: 11 Aug 2021 22:54:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:04
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User entered '0'	System	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15
User entered '0'	System	15 Nov 2020 21:03:10

US3672097

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:51:15

US3672097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:54:27

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:56:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User closed query 'Per ETRTR: Please add Medication, dates and dosing for AE COVID 19, thanks.' (Site from CRA).	(b) (4) (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: 11 Aug 2021 22:54:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	
	(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.' answered with 'conmed is still ongoing ' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 15:35:24
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: 11 Aug 2021 22:54:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4)	
	(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.' answered with 'conmed is still ongoing ' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 15:36:19
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: 11 Aug 2021 22:54:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
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: 11 Aug 2021 22:54:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
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: 11 Aug 2021 22:54:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:15
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: 11 Aug 2021 22:54:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
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: 11 Aug 2021 22:54:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
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: 11 Aug 2021 22:54:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:19
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: 11 Aug 2021 22:54:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
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: MIDOL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (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)	12 Oct 2020 13:49:23
Data point term sent to Coder Coding entries removed.	System	09 Oct 2020 14:52:38
	(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-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MIDOL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (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)	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: 11 Aug 2021 22:54:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:27:42
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 05:18:11
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:20:08
DataPoint Un-verified.	(b) (4), (b) (6)	17 Dec 2020 13:20:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:20:00
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 03:44:26
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: 11 Aug 2021 22:54:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:27:43
DataPoint Un-verified.	(b) (4), (b) (6)	17 Dec 2020 13:20:00
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:20:00
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: 11 Aug 2021 22:54:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
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: 11 Aug 2021 22:54:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
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: 11 Aug 2021 22:54:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:26:05
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: 11 Aug 2021 22:54:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
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 - version WHODrug-Global-B3\202003.	Coder Import (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)	22 Oct 2020 19:27:40
Data point term sent to Coder Coding entries removed.	System	22 Oct 2020 19:26:58
	(b) (4), (b) (6)	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-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (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)	24 Sep 2020 19:02:39
Data point term sent to Coder User entered 'ibuprofen'	System	24 Sep 2020 19:01:28
	(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: 11 Aug 2021 22:54:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
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).	(b) (4), (b) (6)	26 Oct 2020 20:55:37
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)	22 Oct 2020 19:27:02
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:26:54
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: 11 Aug 2021 22:54:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
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: 11 Aug 2021 22:54:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
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: 11 Aug 2021 22:54:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:53
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: 11 Aug 2021 22:54:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
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 - version WHODrug-Global-B3\202003.	Coder Import (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)	22 Oct 2020 19:28:41
Data point term sent to Coder Coding entries removed.	System	22 Oct 2020 19:27:59
	(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-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (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)	24 Sep 2020 19:05:28
Data point term sent to Coder User entered 'IBUPROFEN'	System	24 Sep 2020 19:03:36
	(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: 11 Aug 2021 22:54:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
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).	(b) (4), (b) (6)	26 Oct 2020 20:55:46
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)	22 Oct 2020 19:27:27
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: 11 Aug 2021 22:54:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
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: 11 Aug 2021 22:54:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
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: 11 Aug 2021 22:54:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:25:55
User entered empty.	System	24 Sep 2020 19:02:44

US3672097

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:54:27

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:36:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 19:49:07

US3672097

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:54:27

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:02
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:11:54
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 20:11:54
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
User closed query 'Per CDM: Requery: Response noted for updated, however no updates has been made. Please consider to select "Due to SARS-COV-2" from the provided drop down list. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 05:49:32
Query 'Per CDM: Requery: Response noted for updated, however no updates has been made. Please consider to select "Due to SARS-COV-2" from the provided drop down list. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:21:24
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:21:06
User opened query 'Per CDM: Requery: Response noted for updated, however no updates has been made. Please consider to select "Due to SARS-COV-2" from the provided drop down list. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 11:32:28
User closed query 'Per CDM: please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 11:26:49
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

US3672097

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:54:27

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
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: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:02
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:18
User closed query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 08:53:41
User entered 'AE#1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 20:11:54
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	17 Mar 2021 20:11:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 20:11:40
Query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1). ' answered with 'ok' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 20:11:27
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	17 Mar 2021 20:11:21
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 20:11:21
User entered 'AE # 1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 20:11:21
User opened query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 14:56:32

US3672097

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
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.' canceled (Site from System).	(b) (4), (b) (6)	27 Jan 2021 04:13:41
User closed query 'Per CDM re-query: Response noted. However, please reconcile the 'AE log line number' and update eCRF field accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 04:12:29
Query 'Per CDM re-query: Response noted. However, please reconcile the 'AE log line number' and update eCRF field accordingly.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 14:40:26
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	25 Jan 2021 14:40:20
User entered 'AE LOG LINE 1' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 14:40:20
User opened query 'Per CDM re-query: Response noted. However, please reconcile the 'AE log line number' and update eCRF field accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:41:06
User closed query 'Per CDM: Please consider to provide the AE log line number.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:41:06
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	11 Jan 2021 22:24:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 22:24:40
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	11 Jan 2021 22:24:31

US3672097

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
User entered 'AE log line 1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 22:24:31
Query 'Per CDM: Please consider to provide the AE log line number. ' answered with 'AE log line 2' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 22:24:25
User opened query 'Per CDM: Please consider to provide the AE log line number. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 16:17:02
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	17 Dec 2020 13:21:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 13:21:16
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	17 Dec 2020 13:21:06
User closed query 'Per CDM: Kindly remove all details and only provide the AE log line#. Thank you' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 08:58:08
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

US3672097

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:54:27

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

Audit	User	Time (GMT)
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	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
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: 11 Aug 2021 22:54:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
Reviewed for Safety.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
Reviewed for Safety.	(b) (4) (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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
Reviewed for Safety.	(b) (4) (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: 11 Aug 2021 22:54:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
Reviewed for Safety.	(b) (4) (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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
Reviewed for Safety.	(b) (4) (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: 11 Aug 2021 22:54:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
Reviewed for Safety.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
Reviewed for Safety.	(b) (4) (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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
Reviewed for Safety.	(b) (4) (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: 11 Aug 2021 22:54:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Death

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
Reviewed for Safety.	(b) (4) (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: 11 Aug 2021 22:54:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
Reviewed for Safety.	(b) (4) (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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Death

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
Reviewed for Safety.	(b) (4) (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: 11 Aug 2021 22:54:27

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
Reviewed for Safety.	(b) (4) (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: 11 Aug 2021 22:54:27

[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: 11 Aug 2021 22:54:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:54:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 13:29:28
User entered '1'	(b) (4), (b) (6)	03 Nov 2020 23:31:24