

US3672151 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3672151

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 17:41:37

Generated On: 11 Aug 2021 22:55:49

[Participant ID](#)

US3672151

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

US3672151

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3672151

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Date of Birth (MMM yyyy)	(b) (6) 1995
Age	25
Age Units	YEARS
Age (Derived)	25
Sex	Female <input type="radio"/> Male <input checked="" 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

US3672151

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Date of Informed Consent (<i>dd MMM yyyy</i>)	17 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3672151

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3672151

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Were any significant conditions reported?

Yes ☐

No ☒

US3672151

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	17:20 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 17:20
Height (xxx.x)	195.8 cm
Weight (xxx.x)	95.7 kg
BMI (xxx.x)	24.96241 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	ND - Not Done
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672151

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

US3672151

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☐

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☐

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☐

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☐

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☐

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☐

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☐

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☐

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☐

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☐

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☐

Other Yes ☐ No ☐

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3672151

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION.

US3672151

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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

US3672151

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 105301

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 ☐

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Height	ND - Not Done
Weight	ND - Not Done

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	17:20 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 17:20
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	18:38 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 18:38
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3672151

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3672151

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 17 AUG 2020

What was the treatment time? (00:00-23:59) 18:03 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 18:03

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

US3672151

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 AUG 2020

Collection time (00:00-23:59)

17:40 (24 HR)

Collection date and time (derived)

17 AUG 2020 17:40

US3672151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:14	17 AUG 2020 17:14
Nasopharyngeal Swab 2	No		

US3672151

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

17 AUG 2020 18:35

PC Open Date & Time

17 AUG 2020 18:23

PC Close Date & Time

17 AUG 2020 20:53

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☐ No ☒

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

PC Time Stamp	17 AUG 2020 22:54
PC Open Date & Time	17 AUG 2020 21:48
PC Close Date & Time	18 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 15:55

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 17:43

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 22:28

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

22 AUG 2020 06:19

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 08:42

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 18:42

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 18:36

PC Open Date & Time

17 AUG 2020 18:23

PC Close Date & Time

17 AUG 2020 20:53

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 22:54

PC Open Date & Time

17 AUG 2020 21:48

PC Close Date & Time

18 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 12:15

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 17:39

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 13:42

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 06:19

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 08:43

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 18:42

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 18:37
PC Open Date & Time	17 AUG 2020 18:23
PC Close Date & Time	17 AUG 2020 20:53

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 22:55
PC Open Date & Time	17 AUG 2020 21:48
PC Close Date & Time	18 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 12:15
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 17:39
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 13:42
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

		Yes <input type="checkbox"/>
PC Time stamp	22 AUG 2020 06:19	
PC Open Date & Time	21 AUG 2020 12:00	
PC Close Date & Time	22 AUG 2020 11:59	

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 08:43
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 18:43
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3672151

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672151

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672151

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672151

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672151

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672151

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672151

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	17:17 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 17:17
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

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

US3672151

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3672151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3672151

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

17:40 (24 HR)

Collection date and time (derived)

16 SEP 2020 17:40

US3672151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:27	16 SEP 2020 17:27
Nasopharyngeal Swab 2	No		

US3672151

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672151

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672151

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672151

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672151

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672151

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672151

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 14:11:04

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672151

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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	VISIT3

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 15:10
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672151

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3672151

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

15:35 (24 HR)

Collection date and time (derived)

14 OCT 2020 15:35

US3672151

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 14:11:07

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	19 OCT 2020 14:36:35
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 OCT 2020 22:40:24

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 10:48:07

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 00:02:29

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 12:00:48

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	04 DEC 2020 12:00:15
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 17:14:49

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 DEC 2020 15:50:58
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 18:48:08

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 12:00:14

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	06 JAN 2021 06:03:49
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3672151

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:55:49

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

US3672151

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:41:38

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672151

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:41:38

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672151

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:41:38

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 DEC 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672151

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:41:38

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672151

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:41:38

Generated On: 11 Aug 2021 22:55:49

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

US3672151

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:41:38

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3672151

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:55:49

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

US3672151

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:55:49

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3672151

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:04:53

Generated On: 11 Aug 2021 22:55:49

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID UNBLND_DECIDE

US3672151

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 15:04:53

Generated On: 11 Aug 2021 22:55:49

Date of updated informed consent (dd MMM yyyy)	
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 (dd MMM yyyy)	13 JAN 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	

US3672151

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 15:04:53

Generated On: 11 Aug 2021 22:55:49

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3672151

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 15:04:52

Generated On: 11 Aug 2021 22:55:49

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00 - 23:59)

Collection Date and Time (derived)

US3672151

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 17:41:37

Generated On: 11 Aug 2021 22:55:49

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 17:41:37

Generated On: 11 Aug 2021 22:55:49

AEID

Adverse event

PRUITIC RASH
LOWER EXTREMITIES

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)

18 AUG 2020

Start time (00:00-23:59)

12:15 (24 HR)

AE start date and time (derived)

18 AUG 2020 12:15

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

105 of 850

EAB) (1725)

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 17:41:37

Generated On: 11 Aug 2021 22:55:49

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

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 17:41:37

Generated On: 11 Aug 2021 22:55:49

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

Yes ☒

No ☐

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

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 17:41:37

Generated On: 11 Aug 2021 22:55:49

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication PRURITIC RASH (LOWER
EXTREMITIES)

Dose per administration 50

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)

108 of 850

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 17:41:37

Generated On: 11 Aug 2021 22:55:49

	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)		19 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 17:41:37

Generated On: 11 Aug 2021 22:55:49

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication PRURITIC RASH (LOWER
EXTREMITIES)

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

110 of 850

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 17:41:37

Generated On: 11 Aug 2021 22:55:49

	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)	20 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 17:41:37

Generated On: 11 Aug 2021 22:55:49

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify INJECTION

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)

112 of 850

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 17:41:37

Generated On: 11 Aug 2021 22:55:49

	Intramuscular	<input checked="" 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)		7 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		7 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3672151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Mar 2021 13:20:19

Generated On: 11 Aug 2021 22:55:49

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3672151

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Mar 2021 17:41:37

Generated On: 11 Aug 2021 22:55:49

Date of dosing discontinuation (dd MMM yyyy)	18 AUG 2020
--	-------------

Primary reason for dosing discontinuation	AE (specify) <input checked="" type="radio"/>
	SAE (specify) <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-up <input type="radio"/>
	Physician decision (specify) <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol deviation (specify) <input type="radio"/>
	Study Terminated By Sponsor <input type="radio"/>
	Withdrawal of consent by participant (specify) <input type="radio"/>
	Due to SARS-COV-2 <input type="radio"/>
	Other <input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	AE#1
---	------

US3672151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 05 Mar 2021 17:41:38

Generated On: 11 Aug 2021 22:55:49

Date of study discontinuation/completion (dd MMM yyyy) 13 JAN 2021

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>

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

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

Audit

US3672151 (Prod: Coastal Carolina Research Center)

US3672151

Form: Participant Creation

Generated On: 11 Aug 2021 22:55:49

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'US3672151'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 21:40:59

US3672151

Form: Participant Creation

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 21:48:26

US3672151

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 21:41:00

US3672151

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 21:48:26

US3672151

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'SCRN'	System	17 Aug 2020 21:48:26

US3672151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered (b) (6) 1995'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 21:41:01

US3672151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '25'	(b) (4), (b) (6)	17 Aug 2020 21:48:35

US3672151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'YEARS'	System	17 Aug 2020 21:48:35

US3672151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered '25'	System	17 Aug 2020 21:48:47

US3672151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 21:48:35

US3672151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	17 Aug 2020 21:48:35

US3672151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'I'	(b) (4), (b) (6)	17 Aug 2020 21:48:35

US3672151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 21:48:35

US3672151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 21:48:35

US3672151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 21:48:35

US3672151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 21:48:35

US3672151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 21:48:35

US3672151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 21:48:35

US3672151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 21:48:35

US3672151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 21:48:35

US3672151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 21:48:47

US3672151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'Aug 2020'	System	17 Aug 2020 21:48:47

US3672151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered '2020'	System	17 Aug 2020 21:48:47

US3672151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	17 Aug 2020 21:48:47

US3672151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 21:48:47

US3672151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 21:48:47

US3672151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 21:48:47

US3672151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 21:48:47

US3672151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 21:41:00

US3672151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'I'	System	17 Aug 2020 21:48:51

US3672151

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 21:48:51

US3672151

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:55:49

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 21:49:35

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 21:49:54

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '17 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 21:49:54

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '17:20'	(b) (4), (b) (6)	17 Aug 2020 21:49:54

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered '17 Aug 2020 17:20'	System	17 Aug 2020 21:49:54

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '195.8' cm	(b) (4)	
	(b) (4), (b) (6)	17 Aug 2020 21:49:54
DataPoint set to visible.	System	17 Aug 2020 21:48:51

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '95.7' kg	(b) (4) (b) (4), (b) (6)	17 Aug 2020 21:49:54
DataPoint set to visible.	System	17 Aug 2020 21:48:51

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
Amendment Manager: User entered '24.96241'	System	17 Sep 2020 00:01:11
User entered '25.0'	System	17 Aug 2020 21:49:54
DataPoint set to visible.	System	17 Aug 2020 21:48:51

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'kg/m2'	System	17 Aug 2020 21:49:54
DataPoint set to visible.	System	17 Aug 2020 21:48:51

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Aug 2020 18:04:30
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Aug 2020 18:04:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:04:30
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 21:49:54
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 21:49:54

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 18:04:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Aug 2020 18:04:30
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:04:30
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 21:49:54
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 21:49:54

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	19 Aug 2020 18:04:30
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 21:49:54

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Aug 2020 18:04:30
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Aug 2020 18:04:30
User entered missing code ND - Not Done; reason for change New Information	(b) (4), (b) (6)	19 Aug 2020 18:04:30
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 21:49:54
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 21:49:54

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'bpm'	System	19 Aug 2020 18:04:30
User entered empty.	System	17 Aug 2020 21:49:54

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Aug 2020 18:04:30
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Aug 2020 18:04:30
User entered missing code ND - Not Done; reason for change New Information	(b) (4), (b) (6)	19 Aug 2020 18:04:30
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 21:49:54
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 21:49:54

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'breaths/min'	System	19 Aug 2020 18:04:30
User entered empty.	System	17 Aug 2020 21:49:54

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Aug 2020 18:04:30
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Aug 2020 18:04:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:04:30
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 21:49:54
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 21:49:54

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'mmHg'	System	19 Aug 2020 18:04:30
User entered empty.	System	17 Aug 2020 21:49:54

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Aug 2020 18:04:30
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Aug 2020 18:04:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:04:30
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 21:49:54
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 21:49:54

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'mmHg'	System	19 Aug 2020 18:04:30
User entered empty.	System	17 Aug 2020 21:49:54

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24

US3672151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24

US3672151

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:03:18

US3672151

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:03:18

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

[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)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

[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)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'I'	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'I'	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Resident in a community with ongoing person to person transmission.'	(b) (4), (b) (6)	19 Aug 2020 18:03:54

US3672151

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 21:49:00

US3672151

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 21:49:00

US3672151

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 21:49:00

US3672151

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'VISIT1'	System	17 Aug 2020 21:49:00

US3672151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 21:44:22

US3672151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:10:38
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:10:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 21:44:22
User entered '105301' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 21:44:22

US3672151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 21:44:22

US3672151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

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)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 21:49:08

US3672151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

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)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 21:49:08

US3672151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 21:49:08

US3672151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 21:49:08

US3672151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 21:49:08

US3672151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:23:23
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:45:38

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '17:20'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered '17 Aug 2020 17:20'	System	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '50'	(b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'bpm'	System	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '16'	(b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'breaths/min'	System	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '128'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'mmHg'	System	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '75'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'mmHg'	System	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
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)	20 Aug 2020 04:46:22
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)	19 Aug 2020 18:06:35
User entered '18:38'	(b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered '17 Aug 2020 18:38'	System	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '97.8' F	(b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '56'	(b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'bpm'	System	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '14'	(b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'breaths/min'	System	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '120'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'mmHg'	System	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '75'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'mmHg'	System	19 Aug 2020 18:06:27

US3672151

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:55

US3672151

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:55

US3672151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 22:08:14

US3672151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 22:08:14

US3672151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 22:08:14

US3672151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 22:08:14

US3672151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:08:14

US3672151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '18:03'	(b) (4), (b) (6)	17 Aug 2020 22:08:14

US3672151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered '17 Aug 2020 18:03'	System	17 Aug 2020 22:08:14

US3672151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:08:14

US3672151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'ONCE'	System	17 Aug 2020 22:08:14

US3672151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 22:08:14

US3672151

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:07:14

US3672151

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:07:14

US3672151

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '17:40'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:07:14

US3672151

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered '17 Aug 2020 17:40'	System	19 Aug 2020 18:07:14

US3672151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:55:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:07:28

US3672151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	19 Aug 2020 18:07:28

US3672151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:07:28

US3672151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '17:14'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:07:28

US3672151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered '17 Aug 2020 17:14'	System	19 Aug 2020 18:07:28

US3672151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	19 Aug 2020 18:07:28

US3672151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:07:28

US3672151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:07:28

US3672151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered empty.	System	19 Aug 2020 18:07:28

US3672151

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:07:32

US3672151

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered '1'	System	19 Aug 2020 18:07:32

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T18:35:08', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'c1766d53-d164-4dad-8df8-9cc3d5ae02d1' User entered 'Yes (Y)'	System	17 Aug 2020 22:35:35
	System	17 Aug 2020 22:35:35

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T18:35:15', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'c1766d53-d164-4dad-8df8-9cc3d5ae02d1' User entered '97.8'	System	17 Aug 2020 22:35:35
	System	17 Aug 2020 22:35:35

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T18:35:26', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'c1766d53-d164-4dad-8df8-9cc3d5ae02d1'	System	17 Aug 2020 22:35:35
User entered 'No (N)'	System	17 Aug 2020 22:35:35

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T18:35:30', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'c1766d53-d164-4dad-8df8-9cc3d5ae02d1' User entered '17 Aug 2020 18:35'	System	17 Aug 2020 22:35:35
	System	17 Aug 2020 22:35:35

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '17 Aug 2020 18:23'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '17 Aug 2020 20:53'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T22:54:34', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'b83c0b9b-3e7c-4595-8016-6d7a0e83c0a0' User entered 'Yes (Y)'	System	18 Aug 2020 02:54:49
	System	18 Aug 2020 02:54:49

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T22:54:38', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'b83c0b9b-3e7c-4595-8016-6d7a0e83c0a0' User entered '97.5'	System	18 Aug 2020 02:54:49
	System	18 Aug 2020 02:54:49

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T22:54:40', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'b83c0b9b-3e7c-4595-8016-6d7a0e83c0a0' User entered 'No (N)'	System	18 Aug 2020 02:54:49
	System	18 Aug 2020 02:54:49

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T22:54:46', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'b83c0b9b-3e7c-4595-8016-6d7a0e83c0a0' User entered '17 Aug 2020 22:54'	System	18 Aug 2020 02:54:49
	System	18 Aug 2020 02:54:49

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '17 Aug 2020 21:48'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 2'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-18T15:54:51', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'db609b13-8ea6-4657-bcb3-0a24bb020d0e' User entered 'Yes (Y)'	System	18 Aug 2020 19:55:05
	System	18 Aug 2020 19:55:05

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-18T15:54:55', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'db609b13-8ea6-4657-bcb3-0a24bb020d0e' User entered '97.6'	System	18 Aug 2020 19:55:05
	System	18 Aug 2020 19:55:05

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-18T15:54:58', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'db609b13-8ea6-4657-bcb3-0a24bb020d0e'	System	18 Aug 2020 19:55:05
User entered 'No (N)'	System	18 Aug 2020 19:55:05

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-18T15:55:01', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'db609b13-8ea6-4657-bcb3-0a24bb020d0e' User entered '18 Aug 2020 15:55'	System	18 Aug 2020 19:55:05
	System	18 Aug 2020 19:55:05

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 3'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-19T17:43:23', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'c0eec2c4-df1d-49be-8b31-1b5838795de6'	System	19 Aug 2020 21:43:35
User entered 'Yes (Y)'	System	19 Aug 2020 21:43:35

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-19T17:43:26', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'c0eec2c4-df1d-49be-8b31-1b5838795de6' User entered '96.9'	System	19 Aug 2020 21:43:35
	System	19 Aug 2020 21:43:35

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-19T17:43:31', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'c0eec2c4-df1d-49be-8b31-1b5838795de6'	System	19 Aug 2020 21:43:35
User entered 'No (N)'	System	19 Aug 2020 21:43:35

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-19T17:43:32', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'c0eec2c4-df1d-49be-8b31-1b5838795de6' User entered '19 Aug 2020 17:43'	System	19 Aug 2020 21:43:35
	System	19 Aug 2020 21:43:35

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 4'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-20T22:28:04', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '3f5bc770-8413-40b8-bf4e-6fb2305cddab' User entered 'Yes (Y)'	System	21 Aug 2020 02:28:19
	System	21 Aug 2020 02:28:19

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-20T22:28:07', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '3f5bc770-8413-40b8-bf4e-6fb2305cddab' User entered '97.1'	System	21 Aug 2020 02:28:19
	System	21 Aug 2020 02:28:19

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-20T22:28:15', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '3f5bc770-8413-40b8-bf4e-6fb2305cddab'	System	21 Aug 2020 02:28:19
User entered 'No (N)'	System	21 Aug 2020 02:28:19

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-20T22:28:17', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '3f5bc770-8413-40b8-bf4e-6fb2305cddab' User entered '20 Aug 2020 22:28'	System	21 Aug 2020 02:28:19
	System	21 Aug 2020 02:28:19

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 5'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-22T06:19:07', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '0e9c4bc6-9c30-460c-8fb2-a8fe7d9587d8' User entered 'Yes (Y)'	System	22 Aug 2020 10:19:19
	System	22 Aug 2020 10:19:19

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-22T06:19:12', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '0e9c4bc6-9c30-460c-8fb2-a8fe7d9587d8' User entered '97.4'	System	22 Aug 2020 10:19:19
	System	22 Aug 2020 10:19:19

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-22T06:19:15', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '0e9c4bc6-9c30-460c-8fb2-a8fe7d9587d8'	System	22 Aug 2020 10:19:19
User entered 'No (N)'	System	22 Aug 2020 10:19:19

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-22T06:19:17', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '0e9c4bc6-9c30-460c-8fb2-a8fe7d9587d8' User entered '22 Aug 2020 06:19'	System	22 Aug 2020 10:19:19
	System	22 Aug 2020 10:19:19

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 6'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T08:42:39', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '4487ad89-55a8-410b-a223-c5a43079ce33'	System	23 Aug 2020 12:42:56
User entered 'Yes (Y)'	System	23 Aug 2020 12:42:56

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T08:42:45', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '4487ad89-55a8-410b-a223-c5a43079ce33'	System	23 Aug 2020 12:42:56
User entered '97.6'	System	23 Aug 2020 12:42:56

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T08:42:49', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '4487ad89-55a8-410b-a223-c5a43079ce33'	System	23 Aug 2020 12:42:56
User entered 'No (N)'	System	23 Aug 2020 12:42:56

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T08:42:51', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '4487ad89-55a8-410b-a223-c5a43079ce33'	System	23 Aug 2020 12:42:56
User entered '23 Aug 2020 08:42'	System	23 Aug 2020 12:42:56

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 7'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T18:42:17', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'bda25206-cee0-4502-9576-948948ec720d' User entered 'Yes (Y)'	System	23 Aug 2020 22:42:27
	System	23 Aug 2020 22:42:27

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T18:42:22', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'bda25206-cee0-4502-9576-948948ec720d' User entered '97.2'	System	23 Aug 2020 22:42:27
	System	23 Aug 2020 22:42:27

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T18:42:24', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'bda25206-cee0-4502-9576-948948ec720d' User entered 'No (N)'	System	23 Aug 2020 22:42:27
	System	23 Aug 2020 22:42:27

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T18:42:26', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'bda25206-cee0-4502-9576-948948ec720d' User entered '23 Aug 2020 18:42'	System	23 Aug 2020 22:42:27
	System	23 Aug 2020 22:42:27

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T18:36:04', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'baeb403e-0cf8-42d1-915f-fccdc358ca2c'	System	17 Aug 2020 22:36:27
User entered 'None (1)'	System	17 Aug 2020 22:36:27

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T18:36:08', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'baeb403e-0cf8-42d1-915f-fccdc358ca2c' User entered 'No (N)'	System	17 Aug 2020 22:36:27
	System	17 Aug 2020 22:36:27

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T18:36:15', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'baeb403e-0cf8-42d1-915f-fccdc358ca2c' User entered 'No (N)'	System	17 Aug 2020 22:36:27
	System	17 Aug 2020 22:36:27

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T18:36:20', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'baeb403e-0cf8-42d1-915f-fccdc358ca2c' User entered 'None (1)'	System	17 Aug 2020 22:36:27
	System	17 Aug 2020 22:36:27

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T18:36:22', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'baeb403e-0cf8-42d1-915f-fccdc358ca2c'	System	17 Aug 2020 22:36:27
User entered '17 Aug 2020 18:36'	System	17 Aug 2020 22:36:27

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '17 Aug 2020 18:23'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '17 Aug 2020 20:53'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T22:54:10', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '951d8b26-af00-45f4-ba46-099d01f58e52'	System	18 Aug 2020 02:54:27
User entered 'None (1)'	System	18 Aug 2020 02:54:27

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T22:54:13', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '951d8b26-af00-45f4-ba46-099d01f58e52' User entered 'No (N)'	System	18 Aug 2020 02:54:27
	System	18 Aug 2020 02:54:27

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T22:54:15', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '951d8b26-af00-45f4-ba46-099d01f58e52' User entered 'No (N)'	System	18 Aug 2020 02:54:27
	System	18 Aug 2020 02:54:27

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T22:54:22', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '951d8b26-af00-45f4-ba46-099d01f58e52'	System	18 Aug 2020 02:54:27
User entered 'None (1)'	System	18 Aug 2020 02:54:27

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T22:54:25', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '951d8b26-af00-45f4-ba46-099d01f58e52'	System	18 Aug 2020 02:54:27
User entered '17 Aug 2020 22:54'	System	18 Aug 2020 02:54:27

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '17 Aug 2020 21:48'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 2'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-18T12:14:59', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '976cc384-873e-4b8f-bfbf-f64178c5dd87'	System	18 Aug 2020 16:15:20
User entered 'None (1)'	System	18 Aug 2020 16:15:20

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-18T12:15:02', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '976cc384-873e-4b8f-bfbf-f64178c5dd87'	System	18 Aug 2020 16:15:20
User entered 'No (N)'	System	18 Aug 2020 16:15:20

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-18T12:15:05', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '976cc384-873e-4b8f-bfbf-f64178c5dd87'	System	18 Aug 2020 16:15:20
User entered 'No (N)'	System	18 Aug 2020 16:15:20

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-18T12:15:13', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '976cc384-873e-4b8f-bfbf-f64178c5dd87'	System	18 Aug 2020 16:15:20
User entered 'None (1)'	System	18 Aug 2020 16:15:20

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-18T12:15:18', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '976cc384-873e-4b8f-bfbf-f64178c5dd87'	System	18 Aug 2020 16:15:20
User entered '18 Aug 2020 12:15'	System	18 Aug 2020 16:15:20

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 3'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-19T17:39:28', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'ba24b548-32b6-4cce-b926-b26e68885f2e'	System	19 Aug 2020 21:39:42
User entered 'None (1)'	System	19 Aug 2020 21:39:42

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-19T17:39:30', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'ba24b548-32b6-4cce-b926-b26e68885f2e' User entered 'No (N)'	System	19 Aug 2020 21:39:42
	System	19 Aug 2020 21:39:42

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-19T17:39:34', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'ba24b548-32b6-4cce-b926-b26e68885f2e' User entered 'No (N)'	System	19 Aug 2020 21:39:42
	System	19 Aug 2020 21:39:42

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-19T17:39:36', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'ba24b548-32b6-4cce-b926-b26e68885f2e' User entered 'None (1)'	System	19 Aug 2020 21:39:42
	System	19 Aug 2020 21:39:42

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-19T17:39:38', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'ba24b548-32b6-4cce-b926-b26e68885f2e' User entered '19 Aug 2020 17:39'	System	19 Aug 2020 21:39:42
	System	19 Aug 2020 21:39:42

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 4'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-20T13:41:50', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '2c2e3fb8-b702-4d33-8832-3f0dc9f8b304'	System	20 Aug 2020 17:42:02
User entered 'None (1)'	System	20 Aug 2020 17:42:02

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-20T13:41:53', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '2c2e3fb8-b702-4d33-8832-3f0dc9f8b304' User entered 'No (N)'	System	20 Aug 2020 17:42:02
	System	20 Aug 2020 17:42:02

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-20T13:41:55', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '2c2e3fb8-b702-4d33-8832-3f0dc9f8b304'	System	20 Aug 2020 17:42:02
User entered 'No (N)'	System	20 Aug 2020 17:42:02

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-20T13:41:57', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '2c2e3fb8-b702-4d33-8832-3f0dc9f8b304' User entered 'None (1)'	System	20 Aug 2020 17:42:02
	System	20 Aug 2020 17:42:02

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-20T13:42:00', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '2c2e3fb8-b702-4d33-8832-3f0dc9f8b304' User entered '20 Aug 2020 13:42'	System	20 Aug 2020 17:42:02
	System	20 Aug 2020 17:42:02

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 5'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-22T06:19:20', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'fa40233a-8d4c-4cc2-808f-fda33d11a790'	System	22 Aug 2020 10:19:31
User entered 'None (1)'	System	22 Aug 2020 10:19:31

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-22T06:19:22', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'fa40233a-8d4c-4cc2-808f-fda33d11a790'	System	22 Aug 2020 10:19:31
User entered 'No (N)'	System	22 Aug 2020 10:19:31

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-22T06:19:24', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'fa40233a-8d4c-4cc2-808f-fda33d11a790' User entered 'No (N)'	System	22 Aug 2020 10:19:31
	System	22 Aug 2020 10:19:31

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-22T06:19:25', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'fa40233a-8d4c-4cc2-808f-fda33d11a790'	System	22 Aug 2020 10:19:31
User entered 'None (1)'	System	22 Aug 2020 10:19:31

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-22T06:19:28', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'fa40233a-8d4c-4cc2-808f-fda33d11a790' User entered '22 Aug 2020 06:19'	System	22 Aug 2020 10:19:31
	System	22 Aug 2020 10:19:31

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 6'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T08:42:55', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '8004a29c-7b4c-435b-9484-87352ac06243'	System	23 Aug 2020 12:43:02
User entered 'None (1)'	System	23 Aug 2020 12:43:02

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T08:42:56', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '8004a29c-7b4c-435b-9484-87352ac06243'	System	23 Aug 2020 12:43:02
User entered 'No (N)'	System	23 Aug 2020 12:43:02

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T08:42:57', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '8004a29c-7b4c-435b-9484-87352ac06243'	System	23 Aug 2020 12:43:02
User entered 'No (N)'	System	23 Aug 2020 12:43:02

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T08:42:59', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '8004a29c-7b4c-435b-9484-87352ac06243'	System	23 Aug 2020 12:43:02
User entered 'None (1)'	System	23 Aug 2020 12:43:02

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T08:43:01', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '8004a29c-7b4c-435b-9484-87352ac06243' User entered '23 Aug 2020 08:43'	System	23 Aug 2020 12:43:02
	System	23 Aug 2020 12:43:02

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 7'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T18:42:33', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '039cc21d-8f33-400a-97c5-2279c1dc9cdb' User entered 'None (1)'	System	23 Aug 2020 22:42:43
	System	23 Aug 2020 22:42:43

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T18:42:35', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '039cc21d-8f33-400a-97c5-2279c1dc9cdb' User entered 'No (N)'	System	23 Aug 2020 22:42:43
	System	23 Aug 2020 22:42:43

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T18:42:36', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '039cc21d-8f33-400a-97c5-2279c1dc9cdb' User entered 'No (N)'	System	23 Aug 2020 22:42:43
	System	23 Aug 2020 22:42:43

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T18:42:39', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '039cc21d-8f33-400a-97c5-2279c1dc9cdb' User entered 'None (1)'	System	23 Aug 2020 22:42:43
	System	23 Aug 2020 22:42:43

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T18:42:41', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '039cc21d-8f33-400a-97c5-2279c1dc9cdb' User entered '23 Aug 2020 18:42'	System	23 Aug 2020 22:42:43
	System	23 Aug 2020 22:42:43

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T18:36:38', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '21b0088c-9303-4ef0-aede-9feb6e413b1e' User entered 'None (0)'	System	17 Aug 2020 22:37:03
	System	17 Aug 2020 22:37:03

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T18:36:43', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '21b0088c-9303-4ef0-aede-9feb6e413b1e' User entered 'None (0)'	System	17 Aug 2020 22:37:03
	System	17 Aug 2020 22:37:03

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T18:36:46', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '21b0088c-9303-4ef0-aede-9feb6e413b1e' User entered 'None (0)'	System	17 Aug 2020 22:37:03
	System	17 Aug 2020 22:37:03

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T18:36:48', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '21b0088c-9303-4ef0-aede-9feb6e413b1e' User entered 'None (0)'	System	17 Aug 2020 22:37:03
	System	17 Aug 2020 22:37:03

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T18:36:50', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '21b0088c-9303-4ef0-aede-9feb6e413b1e' User entered 'None (0)'	System	17 Aug 2020 22:37:03
	System	17 Aug 2020 22:37:03

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T18:36:52', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '21b0088c-9303-4ef0-aede-9feb6e413b1e' User entered 'None (0)'	System	17 Aug 2020 22:37:03
	System	17 Aug 2020 22:37:03

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T18:36:58', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '21b0088c-9303-4ef0-aede-9feb6e413b1e' User entered 'No (N)'	System	17 Aug 2020 22:37:03
	System	17 Aug 2020 22:37:03

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T18:37:00', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '21b0088c-9303-4ef0-aede-9feb6e413b1e' User entered '17 Aug 2020 18:37'	System	17 Aug 2020 22:37:03
	System	17 Aug 2020 22:37:03

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '17 Aug 2020 18:23'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '17 Aug 2020 20:53'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T22:54:57', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '832f5433-2c31-4f5f-a298-6c1343740a12' User entered 'None (0)'	System	18 Aug 2020 02:55:13
	System	18 Aug 2020 02:55:13

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T22:54:59', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '832f5433-2c31-4f5f-a298-6c1343740a12' User entered 'None (0)'	System	18 Aug 2020 02:55:13
	System	18 Aug 2020 02:55:13

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T22:55:01', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '832f5433-2c31-4f5f-a298-6c1343740a12'	System	18 Aug 2020 02:55:13
User entered 'None (0)'	System	18 Aug 2020 02:55:13

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T22:55:03', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '832f5433-2c31-4f5f-a298-6c1343740a12' User entered 'None (0)'	System	18 Aug 2020 02:55:13
	System	18 Aug 2020 02:55:13

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T22:55:04', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '832f5433-2c31-4f5f-a298-6c1343740a12' User entered 'None (0)'	System	18 Aug 2020 02:55:13
	System	18 Aug 2020 02:55:13

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T22:55:06', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '832f5433-2c31-4f5f-a298-6c1343740a12' User entered 'None (0)'	System	18 Aug 2020 02:55:13
	System	18 Aug 2020 02:55:13

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T22:55:09', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '832f5433-2c31-4f5f-a298-6c1343740a12'	System	18 Aug 2020 02:55:13
User entered 'No (N)'	System	18 Aug 2020 02:55:13

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-17T22:55:11', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '832f5433-2c31-4f5f-a298-6c1343740a12'	System	18 Aug 2020 02:55:13
User entered '17 Aug 2020 22:55'	System	18 Aug 2020 02:55:13

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '17 Aug 2020 21:48'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 2'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-18T12:15:22', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'e7e3742e-0582-4dc6-8b38-1beeb540e193' User entered 'None (0)'	System	18 Aug 2020 16:15:38
	System	18 Aug 2020 16:15:38

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-18T12:15:23', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'e7e3742e-0582-4dc6-8b38-1beeb540e193' User entered 'None (0)'	System	18 Aug 2020 16:15:38
	System	18 Aug 2020 16:15:38

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-18T12:15:25', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'e7e3742e-0582-4dc6-8b38-1beeb540e193' User entered 'None (0)'	System	18 Aug 2020 16:15:38
	System	18 Aug 2020 16:15:38

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-18T12:15:26', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'e7e3742e-0582-4dc6-8b38-1beeb540e193' User entered 'None (0)'	System	18 Aug 2020 16:15:38
	System	18 Aug 2020 16:15:38

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-18T12:15:30', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'e7e3742e-0582-4dc6-8b38-1beeb540e193' User entered 'None (0)'	System	18 Aug 2020 16:15:38
	System	18 Aug 2020 16:15:38

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-18T12:15:31', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'e7e3742e-0582-4dc6-8b38-1beeb540e193' User entered 'None (0)'	System	18 Aug 2020 16:15:38
	System	18 Aug 2020 16:15:38

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

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)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-18T12:15:33', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'e7e3742e-0582-4dc6-8b38-1beeb540e193' User entered 'No (N)'	System	18 Aug 2020 16:15:38
	System	18 Aug 2020 16:15:38

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-18T12:15:35', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'e7e3742e-0582-4dc6-8b38-1beeb540e193' User entered '18 Aug 2020 12:15'	System	18 Aug 2020 16:15:38
	System	18 Aug 2020 16:15:38

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 3'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-19T17:39:41', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '21541d63-68cc-456c-986c-6ea9a985a79f' User entered 'None (0)'	System	19 Aug 2020 21:40:01
	System	19 Aug 2020 21:40:01

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-19T17:39:43', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '21541d63-68cc-456c-986c-6ea9a985a79f' User entered 'None (0)'	System	19 Aug 2020 21:40:01
	System	19 Aug 2020 21:40:01

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-19T17:39:45', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '21541d63-68cc-456c-986c-6ea9a985a79f' User entered 'None (0)'	System	19 Aug 2020 21:40:01
	System	19 Aug 2020 21:40:01

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-19T17:39:46', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '21541d63-68cc-456c-986c-6ea9a985a79f' User entered 'None (0)'	System	19 Aug 2020 21:40:01
	System	19 Aug 2020 21:40:01

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-19T17:39:48', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '21541d63-68cc-456c-986c-6ea9a985a79f' User entered 'None (0)'	System	19 Aug 2020 21:40:01
	System	19 Aug 2020 21:40:01

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-19T17:39:49', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '21541d63-68cc-456c-986c-6ea9a985a79f' User entered 'None (0)'	System	19 Aug 2020 21:40:01
	System	19 Aug 2020 21:40:01

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

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)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-19T17:39:57', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '21541d63-68cc-456c-986c-6ea9a985a79f' User entered 'No (N)'	System	19 Aug 2020 21:40:01
	System	19 Aug 2020 21:40:01

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-19T17:39:59', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '21541d63-68cc-456c-986c-6ea9a985a79f' User entered '19 Aug 2020 17:39'	System	19 Aug 2020 21:40:01
	System	19 Aug 2020 21:40:01

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 4'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-20T13:42:03', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'dc14bb05-b8d4-4eae-beab-588479f28f21' User entered 'None (0)'	System	20 Aug 2020 17:42:34
	System	20 Aug 2020 17:42:34

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-20T13:42:05', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'dc14bb05-b8d4-4eae-beab-588479f28f21' User entered 'None (0)'	System	20 Aug 2020 17:42:34
	System	20 Aug 2020 17:42:34

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-20T13:42:07', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'dc14bb05-b8d4-4eae-beab-588479f28f21' User entered 'None (0)'	System	20 Aug 2020 17:42:34
	System	20 Aug 2020 17:42:34

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-20T13:42:09', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'dc14bb05-b8d4-4eae-beab-588479f28f21' User entered 'None (0)'	System	20 Aug 2020 17:42:34
	System	20 Aug 2020 17:42:34

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-20T13:42:10', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'dc14bb05-b8d4-4eae-beab-588479f28f21' User entered 'None (0)'	System	20 Aug 2020 17:42:34
	System	20 Aug 2020 17:42:34

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-20T13:42:12', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'dc14bb05-b8d4-4eae-beab-588479f28f21' User entered 'None (0)'	System	20 Aug 2020 17:42:34
	System	20 Aug 2020 17:42:34

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

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)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-20T13:42:29', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'dc14bb05-b8d4-4eae-beab-588479f28f21' User entered 'No (N)'	System	20 Aug 2020 17:42:34
	System	20 Aug 2020 17:42:34

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-20T13:42:32', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'dc14bb05-b8d4-4eae-beab-588479f28f21' User entered '20 Aug 2020 13:42'	System	20 Aug 2020 17:42:34
	System	20 Aug 2020 17:42:34

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 5'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-22T06:18:43', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '830463e6-46e7-4ff5-9a19-e71d6369f235' User entered 'None (0)'	System	22 Aug 2020 10:19:06
	System	22 Aug 2020 10:19:06

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-22T06:18:44', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '830463e6-46e7-4ff5-9a19-e71d6369f235'	System	22 Aug 2020 10:19:06
User entered 'None (0)'	System	22 Aug 2020 10:19:06

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-22T06:18:46', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '830463e6-46e7-4ff5-9a19-e71d6369f235' User entered 'None (0)'	System	22 Aug 2020 10:19:06
	System	22 Aug 2020 10:19:06

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-22T06:18:47', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '830463e6-46e7-4ff5-9a19-e71d6369f235' User entered 'None (0)'	System	22 Aug 2020 10:19:06
	System	22 Aug 2020 10:19:06

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-22T06:18:48', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '830463e6-46e7-4ff5-9a19-e71d6369f235' User entered 'None (0)'	System	22 Aug 2020 10:19:06
	System	22 Aug 2020 10:19:06

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-22T06:18:50', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '830463e6-46e7-4ff5-9a19-e71d6369f235' User entered 'None (0)'	System	22 Aug 2020 10:19:06
	System	22 Aug 2020 10:19:06

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

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)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-22T06:18:56', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '830463e6-46e7-4ff5-9a19-e71d6369f235'	System	22 Aug 2020 10:19:06
User entered 'Yes (Y)'	System	22 Aug 2020 10:19:06

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-22T06:19:00', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '830463e6-46e7-4ff5-9a19-e71d6369f235'	System	22 Aug 2020 10:19:06
User entered '22 Aug 2020 06:19'	System	22 Aug 2020 10:19:06

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 6'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T08:43:04', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'c7512d97-1919-4ff0-bbbc-cde5a063a391' User entered 'None (0)'	System	23 Aug 2020 12:43:24
	System	23 Aug 2020 12:43:24

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T08:43:05', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'c7512d97-1919-4ff0-bbbc-cde5a063a391' User entered 'None (0)'	System	23 Aug 2020 12:43:24
	System	23 Aug 2020 12:43:24

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T08:43:07', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'c7512d97-1919-4ff0-bbbc-cde5a063a391' User entered 'None (0)'	System	23 Aug 2020 12:43:24
	System	23 Aug 2020 12:43:24

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T08:43:08', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'c7512d97-1919-4ff0-bbbc-cde5a063a391' User entered 'None (0)'	System	23 Aug 2020 12:43:24
	System	23 Aug 2020 12:43:24

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T08:43:09', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'c7512d97-1919-4ff0-bbbc-cde5a063a391' User entered 'None (0)'	System	23 Aug 2020 12:43:24
	System	23 Aug 2020 12:43:24

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T08:43:12', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'c7512d97-1919-4ff0-bbbc-cde5a063a391' User entered 'None (0)'	System	23 Aug 2020 12:43:24
	System	23 Aug 2020 12:43:24

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

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)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T08:43:20', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'c7512d97-1919-4ff0-bbbc-cde5a063a391' User entered 'No (N)'	System	23 Aug 2020 12:43:24
	System	23 Aug 2020 12:43:24

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T08:43:23', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'c7512d97-1919-4ff0-bbbc-cde5a063a391' User entered '23 Aug 2020 08:43'	System	23 Aug 2020 12:43:24
	System	23 Aug 2020 12:43:24

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 7'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T18:43:33', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '40c0a346-d7db-492c-aa76-bc5da5412513' User entered 'None (0)'	System	23 Aug 2020 22:43:45
	System	23 Aug 2020 22:43:45

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T18:43:34', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '40c0a346-d7db-492c-aa76-bc5da5412513' User entered 'None (0)'	System	23 Aug 2020 22:43:45
	System	23 Aug 2020 22:43:45

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T18:43:35', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '40c0a346-d7db-492c-aa76-bc5da5412513' User entered 'None (0)'	System	23 Aug 2020 22:43:45
	System	23 Aug 2020 22:43:45

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T18:43:36', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '40c0a346-d7db-492c-aa76-bc5da5412513' User entered 'None (0)'	System	23 Aug 2020 22:43:45
	System	23 Aug 2020 22:43:45

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T18:43:37', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '40c0a346-d7db-492c-aa76-bc5da5412513' User entered 'None (0)'	System	23 Aug 2020 22:43:45
	System	23 Aug 2020 22:43:45

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T18:43:38', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '40c0a346-d7db-492c-aa76-bc5da5412513' User entered 'None (0)'	System	23 Aug 2020 22:43:45
	System	23 Aug 2020 22:43:45

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

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)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T18:43:40', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '40c0a346-d7db-492c-aa76-bc5da5412513' User entered 'No (N)'	System	23 Aug 2020 22:43:45
	System	23 Aug 2020 22:43:45

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-08-23T18:43:43', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '40c0a346-d7db-492c-aa76-bc5da5412513' User entered '23 Aug 2020 18:43'	System	23 Aug 2020 22:43:45
	System	23 Aug 2020 22:43:45

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 22:08:14

US3672151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 21:40:08

US3672151

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 21:40:08

US3672151

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Aug 2020 21:40:08

US3672151

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 21:40:08

US3672151

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 21:40:13

US3672151

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'I'	System	24 Aug 2020 21:40:13

US3672151

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 18:52:21

US3672151

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '02 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 18:52:21

US3672151

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Sep 2020 18:52:21

US3672151

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 18:52:21

US3672151

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 18:52:25

US3672151

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered 'I'	System	09 Sep 2020 18:52:25

US3672151

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 19:10:23

US3672151

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '09 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 19:10:23

US3672151

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Sep 2020 19:10:23

US3672151

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 19:10:23

US3672151

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 19:10:27

US3672151

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered 'I'	System	09 Sep 2020 19:10:27

US3672151

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 15:35:38

US3672151

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '16 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 15:36:41
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 15:35:38

US3672151

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:35:38

US3672151

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'VISIT2'	System	17 Sep 2020 15:35:38

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	17 Sep 2020 15:36:41
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 15:36:24
User entered '16 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '17:17'	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered '16 Sep 2020 17:17'	System	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '97.6' F	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '52'	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'bpm'	System	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '14'	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'breaths/min'	System	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '127'	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'mmHg'	System	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '68'	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'mmHg'	System	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered empty.	System	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered empty.	System	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered empty.	System	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered empty.	System	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered empty.	System	17 Sep 2020 15:36:24

US3672151

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:36:49

US3672151

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:36:49

US3672151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 15:36:54

US3672151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	17 Sep 2020 15:37:07
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 15:37:07
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	17 Sep 2020 15:36:54
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:54

US3672151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:54

US3672151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered empty.	System	17 Sep 2020 15:36:54

US3672151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:54

US3672151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:54

US3672151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered empty.	System	17 Sep 2020 15:36:54

US3672151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:54

US3672151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered empty.	System	17 Sep 2020 15:36:54

US3672151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered empty.	System	17 Sep 2020 15:36:54

US3672151

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:37:26

US3672151

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:37:26

US3672151

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '17:40'	(b) (4), (b) (6)	17 Sep 2020 15:37:26

US3672151

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered '16 Sep 2020 17:40'	System	17 Sep 2020 15:37:26

US3672151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:55:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '16 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 15:37:36

US3672151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	17 Sep 2020 15:37:36

US3672151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 15:37:36

US3672151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '17:27'	(b) (4), (b) (6)	17 Sep 2020 15:37:36

US3672151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered '16 Sep 2020 17:27'	System	17 Sep 2020 15:37:36

US3672151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	17 Sep 2020 15:37:36

US3672151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:37:36

US3672151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:37:36

US3672151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered empty.	System	17 Sep 2020 15:37:36

US3672151

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:37:40

US3672151

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'I'	System	17 Sep 2020 15:37:40

US3672151

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:13:42

US3672151

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	28 Sep 2020 14:02:09
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 15:13:42

US3672151

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Sep 2020 15:13:42

US3672151

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:13:42

US3672151

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:13:51

US3672151

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'I'	System	21 Sep 2020 15:13:51

US3672151

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:04:56

US3672151

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:04:56

US3672151

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:04:56

US3672151

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:04:56

US3672151

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:05:00

US3672151

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'I'	System	30 Sep 2020 21:05:00

US3672151

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 17:49:12

US3672151

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:12

US3672151

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Oct 2020 17:49:12

US3672151

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 17:49:12

US3672151

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 17:49:15

US3672151

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'I'	System	07 Oct 2020 17:49:15

US3672151

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 20:31:42

US3672151

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:42

US3672151

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:42

US3672151

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'VISIT3'	System	14 Oct 2020 20:31:42

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:32:15

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:32:15

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '15:10'	(b) (4), (b) (6)	14 Oct 2020 20:32:15

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered '14 Oct 2020 15:10'	System	14 Oct 2020 20:32:15

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:32:15

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:32:15

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 20:32:15

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '53'	(b) (4), (b) (6)	14 Oct 2020 20:32:15

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'bpm'	System	14 Oct 2020 20:32:15

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '14'	(b) (4), (b) (6)	14 Oct 2020 20:32:15

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'breaths/min'	System	14 Oct 2020 20:32:15

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '121'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:32:15

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'mmHg'	System	14 Oct 2020 20:32:15

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '67'	(b) (4), (b) (6)	14 Oct 2020 20:32:15

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'mmHg'	System	14 Oct 2020 20:32:15

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24

US3672151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24

US3672151

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:32:20

US3672151

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 20:32:20

US3672151

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 20:32:34

US3672151

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:32:34

US3672151

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered '15:35'	(b) (4), (b) (6)	14 Oct 2020 20:32:34

US3672151

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered '14 Oct 2020 15:35'	System	14 Oct 2020 20:32:34

US3672151

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	19 Feb 2021 14:11:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 20:32:37

US3672151

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered '1'	System	14 Oct 2020 20:32:37

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 64'	System	17 Aug 2020 22:08:14

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-10-19T14:36:24', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '9bc82bb0-e214-4d62-a2b9-d71913dd4501'	System	19 Oct 2020 18:36:38
User entered 'No (N)'	System	19 Oct 2020 18:36:38

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-10-19T14:36:31', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '9bc82bb0-e214-4d62-a2b9-d71913dd4501'	System	19 Oct 2020 18:36:38
User entered 'No (N)'	System	19 Oct 2020 18:36:38

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-10-19T14:36:35', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '9bc82bb0-e214-4d62-a2b9-d71913dd4501' User entered '19 Oct 2020 14:36:35'	System	19 Oct 2020 18:36:38
	System	19 Oct 2020 18:36:38

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 22:08:14

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 71'	System	17 Aug 2020 22:08:14

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-10-25T22:40:17', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '83f18790-d0e7-4706-85ec-1e6aaccab1f1d' User entered 'No (N)'	System	26 Oct 2020 02:40:26
	System	26 Oct 2020 02:40:26

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-10-25T22:40:21', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '83f18790-d0e7-4706-85ec-1e6aaccab1f1d'	System	26 Oct 2020 02:40:26
User entered 'No (N)'	System	26 Oct 2020 02:40:26

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-10-25T22:40:24', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '83f18790-d0e7-4706-85ec-1e6aaccab1f1d' User entered '25 Oct 2020 22:40:24'	System	26 Oct 2020 02:40:26
	System	26 Oct 2020 02:40:26

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 22:08:14

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 78'	System	17 Aug 2020 22:08:14

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-11-02T10:47:58', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '1d1846c1-6191-42cd-9430-990282db407f' User entered 'No (N)'	System	02 Nov 2020 15:48:09
	System	02 Nov 2020 15:48:09

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-11-02T10:48:03', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '1d1846c1-6191-42cd-9430-990282db407f' User entered 'No (N)'	System	02 Nov 2020 15:48:09
	System	02 Nov 2020 15:48:09

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-11-02T10:48:07', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '1d1846c1-6191-42cd-9430-990282db407f' User entered '02 Nov 2020 10:48:07'	System	02 Nov 2020 15:48:09
	System	02 Nov 2020 15:48:09

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 22:08:14

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered 'Day 92'	System	17 Aug 2020 22:08:14

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-11-14T00:02:25', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'de883e7c-8797-45de-a8d5-1bd9470973ec' User entered 'No (N)'	System	14 Nov 2020 05:02:36
	System	14 Nov 2020 05:02:36

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-11-14T00:02:27', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'de883e7c-8797-45de-a8d5-1bd9470973ec'	System	14 Nov 2020 05:02:36
User entered 'No (N)'	System	14 Nov 2020 05:02:36

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-11-14T00:02:29', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'de883e7c-8797-45de-a8d5-1bd9470973ec' User entered '14 Nov 2020 00:02:29'	System	14 Nov 2020 05:02:36
	System	14 Nov 2020 05:02:36

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 22:08:14

US3672151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:10:49
Data entry locked.	System	17 Aug 2020 22:08:14
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 22:08:14

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-11-29T12:00:42', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'a1ac83c8-5b37-433b-a278-3ff9b56e8885'	System	29 Nov 2020 17:00:52
User entered 'No (N)'	System	29 Nov 2020 17:00:52

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-11-29T12:00:46', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'a1ac83c8-5b37-433b-a278-3ff9b56e8885'	System	29 Nov 2020 17:00:52
User entered 'No (N)'	System	29 Nov 2020 17:00:52

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-11-29T12:00:48', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'a1ac83c8-5b37-433b-a278-3ff9b56e8885' User entered '29 Nov 2020 12:00:48'	System	29 Nov 2020 17:00:52
	System	29 Nov 2020 17:00:52

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-12-04T12:00:12', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '6fa0e663-f261-486c-8b4c-f45de6c6fa30'	System	04 Dec 2020 17:00:20
User entered 'No (N)'	System	04 Dec 2020 17:00:20

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-12-04T12:00:13', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '6fa0e663-f261-486c-8b4c-f45de6c6fa30'	System	04 Dec 2020 17:00:20
User entered 'No (N)'	System	04 Dec 2020 17:00:20

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-12-04T12:00:15', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '6fa0e663-f261-486c-8b4c-f45de6c6fa30' User entered '04 Dec 2020 12:00:15'	System	04 Dec 2020 17:00:20
	System	04 Dec 2020 17:00:20

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-12-10T17:14:45', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'eea20fa2-17de-4187-ba44-368880e18603' User entered 'No (N)'	System	10 Dec 2020 22:14:51
	System	10 Dec 2020 22:14:51

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-12-10T17:14:47', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'eea20fa2-17de-4187-ba44-368880e18603'	System	10 Dec 2020 22:14:51
User entered 'No (N)'	System	10 Dec 2020 22:14:51

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-12-10T17:14:49', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: 'eea20fa2-17de-4187-ba44-368880e18603' User entered '10 Dec 2020 17:14:49'	System	10 Dec 2020 22:14:51
	System	10 Dec 2020 22:14:51

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-12-18T15:50:56', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '9695de02-d757-4e54-ab84-3cf09817dbb2'	System	18 Dec 2020 20:51:01
User entered 'No (N)'	System	18 Dec 2020 20:51:01

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-12-18T15:50:33', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '9695de02-d757-4e54-ab84-3cf09817dbb2'	System	18 Dec 2020 20:51:01
User entered 'No (N)'	System	18 Dec 2020 20:51:01

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-12-18T15:50:58', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '9695de02-d757-4e54-ab84-3cf09817dbb2' User entered '18 Dec 2020 15:50:58'	System	18 Dec 2020 20:51:01
	System	18 Dec 2020 20:51:01

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-12-26T18:48:04', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '083e7bf5-5145-4ecf-a981-50317940ee8b' User entered 'No (N)'	System	26 Dec 2020 23:48:10
	System	26 Dec 2020 23:48:10

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-12-26T18:48:06', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '083e7bf5-5145-4ecf-a981-50317940ee8b' User entered 'No (N)'	System	26 Dec 2020 23:48:10
	System	26 Dec 2020 23:48:10

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2020-12-26T18:48:08', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '083e7bf5-5145-4ecf-a981-50317940ee8b' User entered '26 Dec 2020 18:48:08'	System	26 Dec 2020 23:48:10
	System	26 Dec 2020 23:48:10

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2021-01-01T12:00:10', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '7a045c6a-a8ca-42aa-93e6-fe238de0c750'	System	01 Jan 2021 17:00:17
User entered 'No (N)'	System	01 Jan 2021 17:00:17

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2021-01-01T12:00:12', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '7a045c6a-a8ca-42aa-93e6-fe238de0c750'	System	01 Jan 2021 17:00:17
User entered 'No (N)'	System	01 Jan 2021 17:00:17

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2021-01-01T12:00:14', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '7a045c6a-a8ca-42aa-93e6-fe238de0c750' User entered '01 Jan 2021 12:00:14'	System	01 Jan 2021 17:00:17
	System	01 Jan 2021 17:00:17

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2021-01-06T06:03:45', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '466178e9-5458-4865-bf4e-ac0de3aba6f0' User entered 'No (N)'	System	06 Jan 2021 11:03:51
	System	06 Jan 2021 11:03:51

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2021-01-06T06:03:46', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '466178e9-5458-4865-bf4e-ac0de3aba6f0'	System	06 Jan 2021 11:03:51
User entered 'No (N)'	System	06 Jan 2021 11:03:51

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA0464B0-C642-4B9B-8FCD-DAA90CD11BC6)', Time: '2021-01-06T06:03:49', User OID: 'PatientReportedOutcome (US3672151)', ODM File OID: '466178e9-5458-4865-bf4e-ac0de3aba6f0' User entered '06 Jan 2021 06:03:49'	System	06 Jan 2021 11:03:51
	System	06 Jan 2021 11:03:51

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:49:03

US3672151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:49:03
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:49:03

US3672151

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:07:53

US3672151

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:07:53

US3672151

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:07:53

US3672151

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:07:53

US3672151

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 15:07:58

US3672151

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:24
User entered 'I'	System	10 Nov 2020 15:07:58

US3672151

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 20:31:10

US3672151

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '2 Dec 2020'	(b) (4), (b) (6)	02 Dec 2020 20:31:10

US3672151

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:31:10

US3672151

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 20:31:10

US3672151

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 20:31:16

US3672151

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered 'I'	System	02 Dec 2020 20:31:16

US3672151

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 16:47:50

US3672151

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:47:50

US3672151

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:47:50

US3672151

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 16:47:50

US3672151

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:47:53

US3672151

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered empty.	System	13 Jan 2021 16:47:53

US3672151

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

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 16:49:59

US3672151

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

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 16:49:59

US3672151

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

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 16:49:59

US3672151

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

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered 'UNBLND_DECIDE'	System	02 Apr 2021 16:49:59

US3672151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User closed query 'Per CDM: Informed Consent Date is missing. Kindly review and update else clarify. '(Site from DM).	(b) (4), (b) (6)	26 Apr 2021 07:40:46
Query 'Per CDM: Informed Consent Date is missing. Kindly review and update else clarify. ' answered with 'ND' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 13:44:03
User opened query 'Per CDM: Informed Consent Date is missing. Kindly review and update else clarify. '(Site from DM).	(b) (4), (b) (6)	22 Apr 2021 13:09:39
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 15:28:41

US3672151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:39:05
User entered '1'	(b) (4), (b) (6)	01 Apr 2021 15:28:41

US3672151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:28:41

US3672151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User closed query 'Per CDM:RQ: Response provided as 'updated' however, N/A - Subject Unblinded under Amendment 5 and Discontinued from Study is still ticked .Please confirm and update else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 16:26:57
Query 'Per CDM:RQ: Response provided as 'updated' however, N/A - Subject Unblinded under Amendment 5 and Discontinued from Study is still ticked .Please confirm and update else clarify. Thank you ' answered with 'confirm PD and patient dropped from study' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 20:39:10
User opened query 'Per CDM:RQ: Response provided as 'updated' however, N/A - Subject Unblinded under Amendment 5 and Discontinued from Study is still ticked .Please confirm and update else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 14:52:03
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 field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 14:52:03
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 field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:47:32
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:47:19
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 field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:06:56
User entered 'Amendment 5 (Amendment 5)'	(b) (4), (b) (6)	01 Apr 2021 15:28:41

US3672151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:28:41

US3672151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:28:41

US3672151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:28:41

US3672151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User entered 'Not Administered (NA)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:28:41

US3672151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:28:41

US3672151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered 'I'	System	01 Apr 2021 15:28:41

US3672151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered empty.	System	01 Apr 2021 15:28:41

US3672151

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 16:50:04

US3672151

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 16:50:04

US3672151

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 16:50:04

US3672151

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered empty.	System	02 Apr 2021 16:50:04

US3672151

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:50:08

US3672151

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 16:50:08

US3672151

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:04:53
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 16:50:08

US3672151

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered empty.	System	02 Apr 2021 16:50:08

US3672151

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:55:49

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:07:00

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User closed query 'Per DM CLR: Please review AE and please update to specify the type of RASH (e.g. Maculopapular, Pustular, etc.). Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 18:28:45
Query 'Per DM CLR: Please review AE and please update to specify the type of RASH (e.g. Maculopapular, Pustular, etc.). Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' answered with 'unknown' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:14:37
User opened query 'Per DM CLR: Please review AE and please update to specify the type of RASH (e.g. Maculopapular, Pustular, etc.). Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 00:01:14
Query 'Per DM CLR: Please review AE and please update to indicate whether the recorded Pruritic Rash on Lower Extremities is Urticarial or Non-urticarial. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' canceled (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 00:01:09
User opened query 'Per DM CLR: Please review AE and please update to indicate whether the recorded Pruritic Rash on Lower Extremities is Urticarial or Non-urticarial. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 08:07:49
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash pruritic, LLT: Pruritic rash - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 00:55:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 00:55:19

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and update AE term to reflect specific body location of PRURITIC RASH. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:54:37
Query 'Per DM CLR: Please review and update AE term to reflect specific body location of PRURITIC RASH. Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 21:03:30
Data point term sent to Coder	System	30 Sep 2020 21:03:29
Coding entries removed.	(b) (4), (b) (6)	30 Sep 2020 21:03:22
User entered 'PRUITIC RASH Lower extremities' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 21:03:22
User opened query 'Per DM CLR: Please review and update AE term to reflect specific body location of PRURITIC RASH. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:29:43
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash pruritic, LLT: Pruritic rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 10:14:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 10:14:13
Data point term sent to Coder	System	20 Aug 2020 20:11:38
User entered 'Pruitic rash'	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:02:48
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 05:10:36

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '18 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	20 Aug 2020 20:11:40
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User closed query 'Per CDM: Re-query: Site response indicates Start-time is Unknown, however, per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 17Aug2 020 at 18:03, and AE Start-date is 18Aug2020. Please verify data and update AE Start-time as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 11:51:27
Query 'Per CDM: Re-query: Site response indicates Start-time is Unknown, however, per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 17Aug2 020 at 18:03, and AE Start-date is 18Aug2020. Please verify data and update AE Start-time as appropriate. Thank you. ' answered with 'start time updated' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:16:56
User entered '12:15' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 13:14:33
User opened query 'Per CDM: Re-query: Site response indicates Start-time is Unknown, however, per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 17Aug2 020 at 18:03, and AE Start-date is 18Aug2020. Please verify data and update AE Start-time as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:47:27
User closed query 'Per CDM: Response noted. Please confirm This AE started before or after the first dose of IP. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:43:31
Query 'Per CDM: Response noted. Please confirm This AE started before or after the first dose of IP. Thank you. ' answered with 'THE FIRST DOSE WAS GIVEN ON 17AUG2020. CLEARLY, IT STARTED AFTER. PLEASE VERIFY PRIOR TO ISSUING QUERY' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 22:25:51
User opened query 'Per CDM: Response noted. Please confirm This AE started before or after the first dose of IP. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 08:05:41

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 12:58:00
Query 'Data is required. Please provide.' answered with 'start time is unknown' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 20:12:04
User closed query 'Start time is present for an AE that System did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		20 Aug 2020 20:11:40
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:11:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:11:40
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	20 Aug 2020 20:11:03
User entered '00:00'	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered '18 Aug 2020 12:15'	System	23 Oct 2020 13:14:33
User entered empty.	System	20 Aug 2020 20:11:40
User entered '20 Aug 2020 00:00'	System	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	30 Sep 2020 21:04:28
User entered 'No (N)' reason for change: Data Entry Error	System	30 Sep 2020 21:04:28
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 21:02:48
User entered 'Yes (Y)'	System	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '26 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	30 Sep 2020 21:02:48
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 11:54:50
Query 'Data is required. Please provide.' answered with 'unknown.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 21:04:40
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 21:04:28
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered empty.	System	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	15 Nov 2020 17:07:04
reason for change: Data Entry Error		
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
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	20 Aug 2020 20:19:52
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:19:52
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 20:11:03
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
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	20 Aug 2020 20:19:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	20 Aug 2020 20:19:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 20:11:03
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User closed query 'Per CDM Re-Query: Thank you for your confirmation. Please ensure the Dosing Discontinuation page is completed. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 11:52:03
Query 'Per CDM Re-Query: Thank you for your confirmation. Please ensure the Dosing Discontinuation page is completed. Thank you' answered with 'dosing discontinuation updated' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:17:06
User opened query 'Per CDM Re-Query: Thank you for your confirmation. Please ensure the Dosing Discontinuation page is completed. Thank you' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 22:06:05
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 22:06:05
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' answered with 'No 2nd vaccine' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 21:04:43
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:29:51
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 20:19:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 20:19:52
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:19:52
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 20:11:03

PRODUCTION RELEASE (v12.003
EAB) (1725)

773 of 850

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'I'	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	30 Sep 2020 21:02:48
Data Entry Error	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 20:11:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 20:11:40
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	(b) (4), (b) (6)	20 Aug 2020 20:11:40
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 20:11:03
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:03

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: User entered '0'	System	21 Aug 2020 05:10:38
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 05:10:36

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager: User entered 'I'	System	21 Aug 2020 05:10:38
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 05:10:36

US3672151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 05:10:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:55:49

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:20:27
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:02:46

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 12:30:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 12:30:21
Data point term sent to Coder	System	23 Oct 2020 13:19:36
Coding entries removed.	(b) (4), (b) (6)	23 Oct 2020 13:19:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 04:10:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 04:10:19
Data point term sent to Coder	System	20 Aug 2020 20:22:00
User entered 'benadryl'	(b) (4), (b) (6)	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User closed query 'Per DM CLR: Please update the indication to reflect the specific body location of PRURITIC RASH. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:23:41
Query 'Per DM CLR: Please update the indication to reflect the specific body location of PRURITIC RASH. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'location updated' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:19:29
User entered 'PRURITIC RASH (lower extremities)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 13:19:16
User opened query 'Per DM CLR: Please update the indication to reflect the specific body location of PRURITIC RASH. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 05:38:11
User entered 'pruitic rash'	(b) (4), (b) (6)	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '50'	(b) (4), (b) (6)	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'as needed (PRN)'	(b) (4), (b) (6)	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
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)	26 Nov 2020 17:06:32
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)	24 Nov 2020 21:00:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:59:52
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)	18 Nov 2020 03:06:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:59:52
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:40:14
Query 'Per DM CLR: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 20:31:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 20:31:01
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 10:09:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered empty.	System	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered empty.	System	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered empty.	System	20 Aug 2020 20:21:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 12:47:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 12:47:20
Data point term sent to Coder	System	23 Oct 2020 13:20:37
Coding entries removed.	(b) (4), (b) (6)	23 Oct 2020 13:20:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 14:39:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 14:39:17
Data point term sent to Coder	System	22 Aug 2020 14:35:13
Query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	Coder Import (b) (4)	22 Aug 2020 14:35:12
' canceled (Site from System).		
User opened query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	Coder Import (b) (4)	21 Aug 2020 06:52:08
' (Site from System).		

PRODUCTION RELEASE (v12.003
EAB) (1725)

803 of 850

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	20 Aug 2020 20:23:04
User entered 'zyrtec'	(b) (4), (b) (6)	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User closed query 'Per DM CLR: Please update the indication to reflect the specific body location of PRURITIC RASH. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:25:01
Query 'Per DM CLR: Please update the indication to reflect the specific body location of PRURITIC RASH. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'location updated' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:20:27
User entered 'PRURITIC RASH (lower extremities)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 13:20:22
User opened query 'Per DM CLR: Please update the indication to reflect the specific body location of PRURITIC RASH. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 05:39:56
User entered 'pruitic rash'	(b) (4), (b) (6)	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '10'	(b) (4), (b) (6)	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
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) (4), (b) (6)	26 Nov 2020 17:06:48
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)	24 Nov 2020 21:00:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 21:00:40
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)	18 Nov 2020 03:06:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 21:00:40
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 07:40:24
Query 'Per DM CLR: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 20:31:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 20:31:16
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 10:10:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered '1'	System	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered '1'	System	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered '804 (804)'	System	20 Aug 2020 20:22:36

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 17:52:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 17:52:21
Data point term sent to Coder	System	07 Oct 2020 17:50:42
User entered 'Influenza vaccination'	(b) (4), (b) (6)	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Influenza prophylaxis'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'I'	(b) (4), (b) (6)	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Injection'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered empty.	System	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered empty.	System	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User entered empty.	System	07 Oct 2020 17:50:08

US3672151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:55:49

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:20:19
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 21:28:59

US3672151

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:55:49

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:18:38

US3672151

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:55:49

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:18:38

US3672151

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:55:49

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)	26 Apr 2021 21:11:43
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 06:18:03
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' answered with 'OK' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 14:15:47
User entered 'AE#1' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 14:15:40
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:13:15
User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 16:15:51
Query 'Per CDM: Please record AE record number instead of details ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 20:54:15
User entered 'AE 1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:54:10
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:35:44
User entered 'Pruritic rash (lower extremities)'	(b) (4), (b) (6)	23 Oct 2020 13:18:38

US3672151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:55:49

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:48:41

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:55:49

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:48:41

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:55:49

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)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered 'REQUEST TO UNBLIND'	(b) (4), (b) (6)	13 Jan 2021 16:48:41

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:55:49

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:48:41

US3672151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:55:49

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:48:41

US3672151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:55:49

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 16:48:41

US3672151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:55:49

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:11:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:38
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:48:41