

US3672251 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

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US3672251

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 18:03:50

Generated On: 11 Aug 2021 22:58:30

[Participant ID](#)

US3672251

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

US3672251

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Date of Birth (MMM yyyy)	(b) (6) 1977
Age	42
Age Units	YEARS
Age (Derived)	42
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Date of Informed Consent (dd MMM yyyy)	21 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 20:06:33

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN NOV 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Condition	VITAMIN B12 DEFICIENT
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Condition	VITAMIN D DEFICIENT
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN FEB 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN FEB 2016
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2016
Start Year (derived)	2016
Stop Month and Year (derived)	FEB 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	21 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:50 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 11:50
Height (<i>xxx.x</i>)	159.4 cm
Weight (<i>xxx.x</i>)	51.7 kg
BMI (<i>xxx.x</i>)	20.34763 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 20:06:33

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Date of assessment (dd MMM yyyy) 21 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN FEB 2016

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 20:06:33

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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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 20:06:33

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 106874

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 11:50
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	13:02 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 13:02
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	84 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)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

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) 21 AUG 2020

What was the treatment time? (00:00-23:59) 12:31 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 12:31

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

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 AUG 2020

Collection time (00:00-23:59)

12:10 (24 HR)

Collection date and time (derived)

21 AUG 2020 12:10

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:45	21 AUG 2020 11:45
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

21 AUG 2020 13:07

PC Open Date & Time

21 AUG 2020 12:51

PC Close Date & Time

21 AUG 2020 15:21

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

PC Time Stamp	21 AUG 2020 17:55
PC Open Date & Time	21 AUG 2020 16:16
PC Close Date & Time	22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:58:30

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

97.1 °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

22 AUG 2020 17:42

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 17:41

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:58:30

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 17:43

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:58:30

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

97.2 °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

25 AUG 2020 17:46

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 17:38

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 17:43

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

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

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

21 AUG 2020 13:08

PC Open Date & Time

21 AUG 2020 12:51

PC Close Date & Time

21 AUG 2020 15:21

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

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

21 AUG 2020 17:56

PC Open Date & Time

21 AUG 2020 16:16

PC Close Date & Time

22 AUG 2020 11:59

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:58:30

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

22 AUG 2020 17:43

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:58:30

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

23 AUG 2020 17:42

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:58:30

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

24 AUG 2020 17:44

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:58:30

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

25 AUG 2020 17:47

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:58:30

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

26 AUG 2020 17:39

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:58:30

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

27 AUG 2020 17:43

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

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 ☐

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 13:08
PC Open Date & Time	21 AUG 2020 12:51
PC Close Date & Time	21 AUG 2020 15:21

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

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 ☐

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 17:57
PC Open Date & Time	21 AUG 2020 16:16
PC Close Date & Time	22 AUG 2020 11:59

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:58:30

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 ☒

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EAB) (1725)

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US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:58:30

Yes ☐	
PC Time stamp	22 AUG 2020 17:43
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:58:30

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:58:30

Yes ☐	
PC Time stamp	23 AUG 2020 17:42
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:58:30

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 ☒

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EAB) (1725)

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US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:58:30

Yes ☐	
PC Time stamp	24 AUG 2020 17:44
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:58:30

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 ☒

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EAB) (1725)

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:58:30

Yes ☐	
PC Time stamp	25 AUG 2020 17:47
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:58:30

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:58:30

Yes ☐	
PC Time stamp	26 AUG 2020 17:39
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:58:30

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 ☒

PRODUCTION RELEASE (v12.003

56 of 1538

EAB) (1725)

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:58:30

Yes ☐	
PC Time stamp	27 AUG 2020 17:44
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3672251

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672251

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672251

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672251

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672251

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672251

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672251

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:06:34

Generated On: 11 Aug 2021 22:58:30

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 20:06:34

Generated On: 11 Aug 2021 22:58:30

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	10:06 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 10:06
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 20:06:34

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:06:34

Generated On: 11 Aug 2021 22:58:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3672251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 20:06:34

Generated On: 11 Aug 2021 22:58:30

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 DUE TO INJECTION SITE REACTION ON D8, SUBJECT DECLINED SECOND VACCINATION

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? _____

US3672251

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:06:34

Generated On: 11 Aug 2021 22:58:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

10:26 (24 HR)

Collection date and time (derived)

23 SEP 2020 10:26

US3672251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:17	23 SEP 2020 10:17
Nasopharyngeal Swab 2	No		

US3672251

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:34

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672251

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672251

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672251

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672251

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672251

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672251

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:33

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672251

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:06:34

Generated On: 11 Aug 2021 22:58:30

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 20:06:34

Generated On: 11 Aug 2021 22:58:30

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 13:05
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672251

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:06:34

Generated On: 11 Aug 2021 22:58:30

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.

US3672251

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:06:34

Generated On: 11 Aug 2021 22:58:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

13:05 (24 HR)

Collection date and time (derived)

23 OCT 2020 13:05

US3672251

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:34

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 04:27:52

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

28 OCT 2020 04:08:29

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

06 NOV 2020 12:25:56

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

19 NOV 2020 10:55:59

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 96

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 04:14:51

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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 05:40:50
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 06:46:54
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

13 DEC 2020 05:49:55

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 07:00:39
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

27 DEC 2020 06:42:16

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 01:29:37
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 06:03:30
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 05:58:21

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 05:19:38

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 05:40:47

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 06:58:58
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 06:40:03
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 06:24:25

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 12:07:05

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 MAR 2021 06:44:41
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 07:04:49
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 12:44:14
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 MAR 2021 06:39:48
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 06:58:45

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 06:47:13

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 06:49:57

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 06:32:44

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 06:42:15

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 425

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

No ☐
Yes ☐

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

No ☐
Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 460

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

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03 FEB 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 537
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

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10 FEB 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

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17 FEB 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

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24 FEB 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 558
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

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27 FEB 2022 00:01

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03 MAR 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

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US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

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US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

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24 MAR 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

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31 MAR 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

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03 APR 2022 00:01

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07 APR 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 600

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

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10 APR 2022 00:01

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14 APR 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

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24 APR 2022 00:01

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28 APR 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

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05 MAY 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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16 JUN 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

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21 JUL 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3672251

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:58:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 12:07:16

US3672251

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672251

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672251

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672251

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672251

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672251

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672251

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672251

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672251

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:15:34

Generated On: 11 Aug 2021 22:58:30

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT4

US3672251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 15:15:34

Generated On: 11 Aug 2021 22:58:30

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3672251

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:15:34

Generated On: 11 Aug 2021 22:58:30

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.

US3672251

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 15:15:34

Generated On: 11 Aug 2021 22:58:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 MAR 2021

Collection time (00:00-23:59)

10:09 (24 HR)

Collection date and time (derived)

28 MAR 2021 10:09

US3672251

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:15:34

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672251

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 20 Apr 2021 15:33:30

Generated On: 11 Aug 2021 22:58:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672251

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 20 Apr 2021 15:33:30

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672251

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672251

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3672251

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:58:30

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3672251

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	31 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	UNBLND_DECIDE

US3672251

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 15:15:34

Generated On: 11 Aug 2021 22:58:30

Date of updated informed consent (dd MMM yyyy)	31 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ☒ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ☒
Date of unblinding (dd MMM yyyy)	31 JAN 2021
Participant randomization assignment	mRNA-1273 ☒ Placebo ☐
Actual Dose 1	mRNA-1273 ☒ Placebo ☐ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☐ Not Administered ☒
Will participant receive mRNA-1273?	Yes ☒ No ☐
Placebo Only Flag	
Continuing with mRNA-1273	1

US3672251

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3672251

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	31 JAN 2021
Time of assessment (00:00-23:59)	11:26 (24 HR)
Vital Signs Date and Time (derived)	31 JAN 2021 11:26
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3672251

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	31 JAN 2021
Time of assessment (00:00-23:59)	12:27 (24 HR)
Vital Signs Date and Time (derived)	31 JAN 2021 12:27
Temperature (xxx.x)	98.6 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3672251

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

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 JAN 2021

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

US3672251

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

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 31 JAN 2021

What was the treatment time? (00:00-23:59) 11:56 (24 HR)

Treatment Date and Time (derived) 31 JAN 2021 11:56

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

US3672251

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 JAN 2021

Collection time (00:00-23:59)

11:34 (24 HR)

Collection date and time (derived)

31 JAN 2021 11:34

US3672251

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	31 JAN 2021
Collection time (00:00 - 23:59)	11:15
Collection Date and Time (derived)	31 JAN 2021 11:15

US3672251

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

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672251

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672251

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Is the participant continuing to the next visit?	Yes ☒
	No ☐
Continuing Flag	1
OLD29 Placebo Flag	1

US3672251

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	OLD29

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3672251

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

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.

US3672251

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 FEB 2021

Collection time (00:00-23:59)

11:10 (24 HR)

Collection date and time (derived)

28 FEB 2021 11:10

US3672251

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 18:03:50

Generated On: 11 Aug 2021 22:58:30

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 18:03:50

Generated On: 11 Aug 2021 22:58:30

AEID	
Adverse event	REDNESS AT INJECTION SITE
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)	28 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	30 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 18:03:50

Generated On: 11 Aug 2021 22:58:30

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

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

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

Yes ☒

No ☐

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

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 18:03:50

Generated On: 11 Aug 2021 22:58:30

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

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US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 18:03:50

Generated On: 11 Aug 2021 22:58:30

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN NOV 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 18:03:50

Generated On: 11 Aug 2021 22:58:30

Name of Medication VITAMIN B12

Prophylaxis Yes ☐
No ☒

Indication VITAMIN B12 DEFICIENCY

Dose per administration 6000

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

If dose unit is Other, specify MCG

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 18:03:50

Generated On: 11 Aug 2021 22:58:30

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 18:03:50

Generated On: 11 Aug 2021 22:58:30

Name of Medication	VITAMIN D
Prophylaxis	Yes ☐ No ☒
Indication	VITAMIN D DEFICIENCY
Dose per administration	250
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MCG
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 18:03:50

Generated On: 11 Aug 2021 22:58:30

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 18:03:50

Generated On: 11 Aug 2021 22:58:30

Name of Medication INFLUENZA VACCINE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 18:03:50

Generated On: 11 Aug 2021 22:58:30

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3672251

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:58:30

Date of dosing discontinuation (dd MMM yyyy) 23 SEP 2020

Primary reason for dosing discontinuation

AE (specify) ☒

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3672251

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:58:30

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3672251 (Prod: Coastal Carolina Research Center)

US3672251

Form: Participant Creation

Generated On: 11 Aug 2021 22:58:30

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'US3672251'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 16:04:22

US3672251

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 16:27:53

US3672251

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 16:04:23

US3672251

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:27:53

US3672251

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'SCRN'	System	21 Aug 2020 16:27:53

US3672251

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:30

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered (b) (6) 1977'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 16:04:24

US3672251

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:30

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '42'	(b) (4), (b) (6)	21 Aug 2020 16:28:12

US3672251

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:30

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'YEARS'	System	21 Aug 2020 16:28:12

US3672251

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:30

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered '42'	System	21 Aug 2020 16:30:44

US3672251

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:30

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Aug 2020 16:28:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 16:28:17
User entered 'Female (F)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:28:17
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 16:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:28:12

US3672251

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:30

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	21 Aug 2020 16:28:12

US3672251

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:30

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '1'	(b) (4), (b) (6)	21 Aug 2020 16:28:12

US3672251

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:30

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 16:28:12

US3672251

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:30

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 16:28:12

US3672251

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:30

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 16:28:12

US3672251

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:30

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 16:28:12

US3672251

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 16:28:12

US3672251

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:30

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:28:12

US3672251

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:30

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 16:28:12

US3672251

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:30

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 16:28:12

US3672251

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:30:44

US3672251

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'Aug 2020'	System	21 Aug 2020 16:30:44

US3672251

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered '2020'	System	21 Aug 2020 16:30:44

US3672251

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:58:30

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	21 Aug 2020 16:30:44

US3672251

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Aug 2020 16:30:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 16:30:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:30:49
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 16:30:44
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:30:44

US3672251

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:30:44

US3672251

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:58:30

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:30:44

US3672251

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:58:30

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 16:30:44

US3672251

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:58:30

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 16:04:23

US3672251

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:58:30

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered '1'	System	21 Aug 2020 16:30:54

US3672251

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 16:30:54

US3672251

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:58:30

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 15:13:04

US3672251

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:58:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 15:14:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 15:14:37
Data point term sent to Coder	System	24 Aug 2020 15:13:50
User entered 'hypertension'	(b) (4), (b) (6)	24 Aug 2020 15:13:27

US3672251

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'un Nov 2019'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:13:27

US3672251

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:58:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:13:27

US3672251

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:58:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 15:13:27

US3672251

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:13:27

US3672251

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:58:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:13:27

US3672251

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'Nov 2019'	System	24 Aug 2020 15:13:27

US3672251

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered '2019'	System	24 Aug 2020 15:13:27

US3672251

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered empty.	System	24 Aug 2020 15:13:27

US3672251

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered empty.	System	24 Aug 2020 15:13:27

US3672251

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:58:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Water soluble vitamin deficiencies, PT: Vitamin B12 deficiency, LLT: Vitamin B12 deficiency - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 23:49:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 23:49:38
Data point term sent to Coder	System	24 Aug 2020 15:13:51
User entered 'Vitamin B12 deficient'	(b) (4), (b) (6)	24 Aug 2020 15:13:40

US3672251

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:13:40

US3672251

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:58:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:13:40

US3672251

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:58:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 15:13:40

US3672251

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:13:40

US3672251

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:58:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:13:40

US3672251

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'Jan 2016'	System	24 Aug 2020 15:13:40

US3672251

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered '2016'	System	24 Aug 2020 15:13:40

US3672251

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered empty.	System	24 Aug 2020 15:13:40

US3672251

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered empty.	System	24 Aug 2020 15:13:40

US3672251

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:58:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 15:15:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 15:15:34
Data point term sent to Coder	System	24 Aug 2020 15:14:51
User entered 'VITAMIN d deficient'	(b) (4), (b) (6)	24 Aug 2020 15:13:56

US3672251

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'un Jan 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:13:56

US3672251

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:58:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:13:56

US3672251

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:58:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 15:13:56

US3672251

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:13:56

US3672251

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:58:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:13:56

US3672251

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'Jan 2020'	System	24 Aug 2020 15:13:56

US3672251

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered '2020'	System	24 Aug 2020 15:13:56

US3672251

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered empty.	System	24 Aug 2020 15:13:56

US3672251

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered empty.	System	24 Aug 2020 15:13:56

US3672251

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:58:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 20:34:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 20:34:44
Data point term sent to Coder	System	22 Oct 2020 20:33:14
User entered 'Tubal Ligation'	(b) (4), (b) (6)	22 Oct 2020 20:32:36

US3672251

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'un Feb 2016'	(b) (4), (b) (6)	22 Oct 2020 20:32:36

US3672251

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:58:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 20:32:36

US3672251

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:58:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:32:36

US3672251

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'un Feb 2016'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:32:36

US3672251

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:58:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 20:32:36

US3672251

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'Feb 2016'	System	22 Oct 2020 20:32:36

US3672251

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered '2016'	System	22 Oct 2020 20:32:36

US3672251

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'Feb 2016'	System	22 Oct 2020 20:32:36

US3672251

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered '2016'	System	22 Oct 2020 20:32:36

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 15:14:31

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:14:31

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '11:50'	(b) (4), (b) (6)	24 Aug 2020 15:14:31

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered '21 Aug 2020 11:50'	System	24 Aug 2020 15:14:31

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '159.4' cm	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:14:31
DataPoint set to visible.	System	21 Aug 2020 16:30:54

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '51.7' kg	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:14:31
DataPoint set to visible.	System	21 Aug 2020 16:30:54

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
Amendment Manager: User entered '20.34763'	System	17 Sep 2020 00:18:19
User entered '20.3'	System	24 Aug 2020 15:14:31
DataPoint set to visible.	System	21 Aug 2020 16:30:54

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'kg/m2'	System	24 Aug 2020 15:14:31
DataPoint set to visible.	System	21 Aug 2020 16:30:54

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:48:58
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.'	(b) (4), (b) (6)	23 Sep 2020 15:03:10
answered with 'updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 15:03:04
Query 'Data is required. Please provide.' canceled (Site from System).	(b) (4), (b) (6)	09 Sep 2020 16:27:43
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 16:27:38
User opened query 'Data is required. Please provide.' System (Site from System).		24 Aug 2020 15:14:31
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:14:31

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:14:31

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:14:31

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Sep 2020 15:03:04
Query 'Data is required. Please provide.' canceled (Site from System).	(b) (4), (b) (6)	09 Sep 2020 16:27:47
User opened query 'Data is required. Please provide.' System (Site from System).		24 Aug 2020 15:14:31
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:14:31

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'bpm'	System	23 Sep 2020 15:03:04
User entered empty.	System	24 Aug 2020 15:14:31

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Sep 2020 15:03:04
Query 'Data is required. Please provide.' canceled (Site from System).	(b) (4), (b) (6)	09 Sep 2020 16:27:48
User opened query 'Data is required. Please provide.' System (Site from System).		24 Aug 2020 15:14:31
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:14:31

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'breaths/min'	System	23 Sep 2020 15:03:04
User entered empty.	System	24 Aug 2020 15:14:31

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Sep 2020 15:03:04
Query 'Data is required. Please provide.' canceled (Site from System).	(b) (4), (b) (6)	09 Sep 2020 16:27:50
User opened query 'Data is required. Please provide.' System (Site from System).		24 Aug 2020 15:14:31
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:14:31

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'mmHg'	System	23 Sep 2020 15:03:04
User entered empty.	System	24 Aug 2020 15:14:31

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Sep 2020 15:03:04
Query 'Data is required. Please provide.' canceled (Site from System).	(b) (4), (b) (6)	09 Sep 2020 16:27:52
User opened query 'Data is required. Please provide.' System (Site from System).		24 Aug 2020 15:14:31
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:14:31

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'mmHg'	System	23 Sep 2020 15:03:04
User entered empty.	System	24 Aug 2020 15:14:31

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40

US3672251

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40

US3672251

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 15:14:42

US3672251

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	24 Aug 2020 15:14:53
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	24 Aug 2020 15:14:53
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:14:53
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	24 Aug 2020 15:14:42
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 15:14:42

US3672251

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:58:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User closed query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	(b) (4) System	21 Oct 2020 20:03:35
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:35
User opened query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	System	24 Aug 2020 15:15:21
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 15:15:21

US3672251

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:15:21

US3672251

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:58:30

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User closed query 'Per CDM Re-Query: Please note that Surgical Procedures are part of the subject's Medical History. If Surgical Procedures is confirmed, please add to the MH CRF. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 12:32:37
Query 'Per CDM Re-Query: Please note that Surgical Procedures are part of the subject's Medical History. If Surgical Procedures is confirmed, please add to the MH CRF. Thank you' answered with 'Added to MH.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 20:33:26
User opened query 'Per CDM Re-Query: Please note that Surgical Procedures are part of the subject's Medical History. If Surgical Procedures is confirmed, please add to the MH CRF. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 18:00:36
User closed query 'Per DM CLR: Note, If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH eCRF. Please update MH eCRF to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 18:00:36
Query 'Per DM CLR: Note, If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH eCRF. Please update MH eCRF to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate.' answered with 'we were told to not list surgeries in EDC' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 19:37:47
User opened query 'Per DM CLR: Note, If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH eCRF. Please update MH eCRF to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 23:48:20

US3672251

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	24 Aug 2020 15:15:21

US3672251

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:58:30

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:15:21

US3672251

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:58:30

[If Surgically sterile, date of surgery \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'un Feb 2016'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:15:21

US3672251

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:58:30

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:15:21

US3672251

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:15:21

US3672251

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:58:30

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:15:21

US3672251

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

US3672251

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

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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)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

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Folder: Screening

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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)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

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Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

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[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)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

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Folder: Screening

Form: Risk of Exposure

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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)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

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Folder: Screening

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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)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

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Folder: Screening

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[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)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:16:04

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Folder: Screening

Form: Risk of Exposure

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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)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

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Folder: Screening

Form: Risk of Exposure

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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)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

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Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:16:04

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:30

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)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

US3672251

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:30

[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)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:30

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)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

US3672251

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '1'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

US3672251

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '1'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

US3672251

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'resident in a community with ongoing person to person transmission'	(b) (4), (b) (6)	24 Aug 2020 15:16:04

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:31:10

US3672251

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:31:10

US3672251

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:31:10

US3672251

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'VISIT1'	System	21 Aug 2020 16:31:10

US3672251

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 16:14:26

US3672251

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '106874'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 16:14:26

US3672251

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 16:14:26

US3672251

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:30

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)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:31:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:30

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)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:31:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:31:25

US3672251

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:31:25

US3672251

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:30

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:31:25

US3672251

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:38:15
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:59:56

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:00:39
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 15:03:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 15:03:31
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 16:28:04
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Sep 2020 15:03:31
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:00:39
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 15:03:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 15:03:31
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 16:28:04
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:17:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Sep 2020 15:03:31
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:17:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Aug 2020 15:17:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '11:50'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '21 Aug 2020 11:50'	System	24 Aug 2020 15:17:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '98.2' F	(b) (4), (b) (6)	24 Aug 2020 15:17:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '74'	(b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'bpm'	System	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '14'	(b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'breaths/min'	System	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '138'	(b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'mmHg'	System	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '89'	(b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'mmHg'	System	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:00:39
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 15:03:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 15:03:31
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 16:28:04
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Sep 2020 15:03:31
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '13:02'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '21 Aug 2020 13:02'	System	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '98.1' F	(b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '84'	(b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'bpm'	System	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '14'	(b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'breaths/min'	System	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '121'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'mmHg'	System	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '76'	(b) (4), (b) (6)	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'mmHg'	System	24 Aug 2020 15:17:01

US3672251

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:05

US3672251

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:05

US3672251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:34:51

US3672251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:34:51

US3672251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

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)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:34:51

US3672251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 16:34:51

US3672251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:34:51

US3672251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '12:31'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:34:51

US3672251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '21 Aug 2020 12:31'	System	21 Aug 2020 16:34:51

US3672251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:34:51

US3672251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'ONCE'	System	21 Aug 2020 16:34:51

US3672251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 16:34:51

US3672251

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 15:17:26

US3672251

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:26

US3672251

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '12:10'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:26

US3672251

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '21 Aug 2020 12:10'	System	24 Aug 2020 15:17:26

US3672251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:58:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:39

US3672251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:58:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	24 Aug 2020 15:17:39

US3672251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:58:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:39

US3672251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:58:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '11:45'	(b) (4), (b) (6)	24 Aug 2020 15:17:39

US3672251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '21 Aug 2020 11:45'	System	24 Aug 2020 15:17:39

US3672251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:58:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	24 Aug 2020 15:17:39

US3672251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:58:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:39

US3672251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:58:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:39

US3672251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered empty.	System	24 Aug 2020 15:17:39

US3672251

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:42

US3672251

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '1'	System	24 Aug 2020 15:17:42

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T13:06:27', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'ace0226b-c6cc-46a8-9317-abb30aaa8aa4' User entered 'Yes (Y)'	System	21 Aug 2020 17:07:16
	System	21 Aug 2020 17:07:16

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T13:06:35', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'ace0226b-c6cc-46a8-9317-abb30aaa8aa4' User entered '98.1'	System	21 Aug 2020 17:07:16
	System	21 Aug 2020 17:07:16

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T13:06:58', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'ace0226b-c6cc-46a8-9317-abb30aaa8aa4' User entered 'No (N)'	System	21 Aug 2020 17:07:16
	System	21 Aug 2020 17:07:16

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T13:07:13', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'ace0226b-c6cc-46a8-9317-abb30aaa8aa4' User entered '21 Aug 2020 13:07'	System	21 Aug 2020 17:07:16
	System	21 Aug 2020 17:07:16

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '21 Aug 2020 12:51'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '21 Aug 2020 15:21'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T17:55:28', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '57ccd20b-0e43-4894-a3bb-20dc9abddd60' User entered 'Yes (Y)'	System	21 Aug 2020 21:55:48
	System	21 Aug 2020 21:55:48

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T17:55:34', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '57ccd20b-0e43-4894-a3bb-20dc9abddd60' User entered '97.8'	System	21 Aug 2020 21:55:48
	System	21 Aug 2020 21:55:48

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T17:55:40', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '57ccd20b-0e43-4894-a3bb-20dc9abddd60' User entered 'No (N)'	System	21 Aug 2020 21:55:48
	System	21 Aug 2020 21:55:48

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T17:55:45', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '57ccd20b-0e43-4894-a3bb-20dc9abddd60' User entered '21 Aug 2020 17:55'	System	21 Aug 2020 21:55:48
	System	21 Aug 2020 21:55:48

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '21 Aug 2020 16:16'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 2'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:58:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-22T17:41:50', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'df5b3728-501b-4b40-bf4d-fa95e5af52f6' User entered 'Yes (Y)'	System	22 Aug 2020 21:42:04
	System	22 Aug 2020 21:42:04

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:58:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-22T17:41:54', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'df5b3728-501b-4b40-bf4d-fa95e5af52f6' User entered '97.1'	System	22 Aug 2020 21:42:04
	System	22 Aug 2020 21:42:04

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-22T17:41:59', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'df5b3728-501b-4b40-bf4d-fa95e5af52f6'	System	22 Aug 2020 21:42:04
User entered 'No (N)'	System	22 Aug 2020 21:42:04

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:58:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-22T17:42:03', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'df5b3728-501b-4b40-bf4d-fa95e5af52f6' User entered '22 Aug 2020 17:42'	System	22 Aug 2020 21:42:04
	System	22 Aug 2020 21:42:04

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 3'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:58:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-23T17:41:19', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'd0e0425a-1976-47a0-a639-44919c35bafd' User entered 'Yes (Y)'	System	23 Aug 2020 21:41:37
	System	23 Aug 2020 21:41:37

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:58:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-23T17:41:24', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'd0e0425a-1976-47a0-a639-44919c35bafd' User entered '98.0'	System	23 Aug 2020 21:41:37
	System	23 Aug 2020 21:41:37

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-23T17:41:31', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'd0e0425a-1976-47a0-a639-44919c35bafd' User entered 'No (N)'	System	23 Aug 2020 21:41:37
	System	23 Aug 2020 21:41:37

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:58:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-23T17:41:34', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'd0e0425a-1976-47a0-a639-44919c35bafd' User entered '23 Aug 2020 17:41'	System	23 Aug 2020 21:41:37
	System	23 Aug 2020 21:41:37

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 4'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:58:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-24T17:43:30', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '429acbc3-8a38-4890-8c9a-b52f58b22e0b' User entered 'Yes (Y)'	System	24 Aug 2020 21:43:45
	System	24 Aug 2020 21:43:45

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:58:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-24T17:43:34', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '429acbc3-8a38-4890-8c9a-b52f58b22e0b' User entered '97.7'	System	24 Aug 2020 21:43:45
	System	24 Aug 2020 21:43:45

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-24T17:43:37', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '429acbc3-8a38-4890-8c9a-b52f58b22e0b'	System	24 Aug 2020 21:43:45
User entered 'No (N)'	System	24 Aug 2020 21:43:45

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:58:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-24T17:43:41', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '429acbc3-8a38-4890-8c9a-b52f58b22e0b' User entered '24 Aug 2020 17:43'	System	24 Aug 2020 21:43:45
	System	24 Aug 2020 21:43:45

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 5'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:58:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-25T17:46:48', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '39aa10de-335b-4265-9aa1-fad7246c7b31' User entered 'Yes (Y)'	System	25 Aug 2020 21:47:01
	System	25 Aug 2020 21:47:01

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:58:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-25T17:46:52', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '39aa10de-335b-4265-9aa1-fad7246c7b31' User entered '97.2'	System	25 Aug 2020 21:47:01
	System	25 Aug 2020 21:47:01

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-25T17:46:55', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '39aa10de-335b-4265-9aa1-fad7246c7b31' User entered 'No (N)'	System	25 Aug 2020 21:47:01
	System	25 Aug 2020 21:47:01

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:58:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-25T17:46:58', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '39aa10de-335b-4265-9aa1-fad7246c7b31' User entered '25 Aug 2020 17:46'	System	25 Aug 2020 21:47:01
	System	25 Aug 2020 21:47:01

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 6'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:58:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-26T17:38:35', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'dd2e44a0-535f-4eb8-8212-659ebf433a1b' User entered 'Yes (Y)'	System	26 Aug 2020 21:38:47
	System	26 Aug 2020 21:38:47

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:58:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-26T17:38:39', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'dd2e44a0-535f-4eb8-8212-659ebf433a1b' User entered '98.2'	System	26 Aug 2020 21:38:47
	System	26 Aug 2020 21:38:47

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-26T17:38:42', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'dd2e44a0-535f-4eb8-8212-659ebf433a1b' User entered 'No (N)'	System	26 Aug 2020 21:38:47
	System	26 Aug 2020 21:38:47

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:58:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-26T17:38:45', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'dd2e44a0-535f-4eb8-8212-659ebf433a1b' User entered '26 Aug 2020 17:38'	System	26 Aug 2020 21:38:47
	System	26 Aug 2020 21:38:47

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 7'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:58:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-27T17:43:22', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '54106843-e9cf-4c20-93d2-219988d94dd7' User entered 'Yes (Y)'	System	27 Aug 2020 21:43:35
	System	27 Aug 2020 21:43:35

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:58:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-27T17:43:25', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '54106843-e9cf-4c20-93d2-219988d94dd7' User entered '98.0'	System	27 Aug 2020 21:43:35
	System	27 Aug 2020 21:43:35

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-27T17:43:29', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '54106843-e9cf-4c20-93d2-219988d94dd7'	System	27 Aug 2020 21:43:35
User entered 'No (N)'	System	27 Aug 2020 21:43:35

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:58:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-27T17:43:32', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '54106843-e9cf-4c20-93d2-219988d94dd7' User entered '27 Aug 2020 17:43'	System	27 Aug 2020 21:43:35
	System	27 Aug 2020 21:43:35

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T13:07:31', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '1dbc76c1-03c0-46b5-8a52-c0d2525f4d92'	System	21 Aug 2020 17:08:24
User entered 'None (1)'	System	21 Aug 2020 17:08:24

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T13:08:03', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '1dbc76c1-03c0-46b5-8a52-c0d2525f4d92'	System	21 Aug 2020 17:08:24
User entered 'No (N)'	System	21 Aug 2020 17:08:24

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T13:08:07', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '1dbc76c1-03c0-46b5-8a52-c0d2525f4d92'	System	21 Aug 2020 17:08:24
User entered 'No (N)'	System	21 Aug 2020 17:08:24

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T13:08:13', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '1dbc76c1-03c0-46b5-8a52-c0d2525f4d92'	System	21 Aug 2020 17:08:24
User entered 'None (1)'	System	21 Aug 2020 17:08:24

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T13:08:19', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '1dbc76c1-03c0-46b5-8a52-c0d2525f4d92' User entered '21 Aug 2020 13:08'	System	21 Aug 2020 17:08:24
	System	21 Aug 2020 17:08:24

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '21 Aug 2020 12:51'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '21 Aug 2020 15:21'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T17:56:03', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'ac63e230-12eb-4eac-84e8-c87b9b1dc764'	System	21 Aug 2020 21:56:59
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 21:56:59

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T17:56:18', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'ac63e230-12eb-4eac-84e8-c87b9b1dc764' User entered 'No (N)'	System	21 Aug 2020 21:56:59
	System	21 Aug 2020 21:56:59

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T17:56:31', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'ac63e230-12eb-4eac-84e8-c87b9b1dc764' User entered 'No (N)'	System	21 Aug 2020 21:56:59
	System	21 Aug 2020 21:56:59

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T17:56:50', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'ac63e230-12eb-4eac-84e8-c87b9b1dc764'	System	21 Aug 2020 21:56:59
User entered 'None (1)'	System	21 Aug 2020 21:56:59

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T17:56:54', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'ac63e230-12eb-4eac-84e8-c87b9b1dc764' User entered '21 Aug 2020 17:56'	System	21 Aug 2020 21:56:59
	System	21 Aug 2020 21:56:59

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '21 Aug 2020 16:16'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 2'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-22T17:42:20', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '0502c126-05d7-482f-a305-51b7500af801'	System	22 Aug 2020 21:43:14
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 21:43:14

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:58:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-22T17:42:23', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '0502c126-05d7-482f-a305-51b7500af801' User entered 'No (N)'	System	22 Aug 2020 21:43:14
	System	22 Aug 2020 21:43:14

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-22T17:42:57', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '0502c126-05d7-482f-a305-51b7500af801' User entered 'No (N)'	System	22 Aug 2020 21:43:14
	System	22 Aug 2020 21:43:14

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-22T17:43:10', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '0502c126-05d7-482f-a305-51b7500af801'	System	22 Aug 2020 21:43:14
User entered 'None (1)'	System	22 Aug 2020 21:43:14

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:58:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-22T17:43:13', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '0502c126-05d7-482f-a305-51b7500af801' User entered '22 Aug 2020 17:43'	System	22 Aug 2020 21:43:14
	System	22 Aug 2020 21:43:14

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 3'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-23T17:41:42', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '4167f7d1-9921-42fc-bdc2-8ca6654b9431'	System	23 Aug 2020 21:42:18
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 21:42:18

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:58:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-23T17:41:58', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '4167f7d1-9921-42fc-bdc2-8ca6654b9431' User entered 'No (N)'	System	23 Aug 2020 21:42:18
	System	23 Aug 2020 21:42:18

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-23T17:42:01', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '4167f7d1-9921-42fc-bdc2-8ca6654b9431' User entered 'No (N)'	System	23 Aug 2020 21:42:18
	System	23 Aug 2020 21:42:18

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-23T17:42:04', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '4167f7d1-9921-42fc-bdc2-8ca6654b9431' User entered 'None (1)'	System	23 Aug 2020 21:42:18
	System	23 Aug 2020 21:42:18

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:58:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-23T17:42:14', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '4167f7d1-9921-42fc-bdc2-8ca6654b9431' User entered '23 Aug 2020 17:42'	System	23 Aug 2020 21:42:18
	System	23 Aug 2020 21:42:18

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 4'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-24T17:43:54', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'dc91c14b-b329-4b3c-85ca-aeb84424c02b' User entered 'Does not interfere with activity (2)'	System	24 Aug 2020 21:44:18
	System	24 Aug 2020 21:44:18

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:58:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-24T17:43:57', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'dc91c14b-b329-4b3c-85ca-aeb84424c02b' User entered 'No (N)'	System	24 Aug 2020 21:44:18
	System	24 Aug 2020 21:44:18

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-24T17:44:09', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'dc91c14b-b329-4b3c-85ca-aeb84424c02b' User entered 'No (N)'	System	24 Aug 2020 21:44:18
	System	24 Aug 2020 21:44:18

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-24T17:44:12', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'dc91c14b-b329-4b3c-85ca-aeb84424c02b' User entered 'None (1)'	System	24 Aug 2020 21:44:18
	System	24 Aug 2020 21:44:18

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:58:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-24T17:44:14', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'dc91c14b-b329-4b3c-85ca-aeb84424c02b' User entered '24 Aug 2020 17:44'	System	24 Aug 2020 21:44:18
	System	24 Aug 2020 21:44:18

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 5'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-25T17:47:02', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'e113a3e5-0e10-42b6-9743-988051d54abc' User entered 'None (1)'	System	25 Aug 2020 21:47:31
	System	25 Aug 2020 21:47:31

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:58:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-25T17:47:05', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'e113a3e5-0e10-42b6-9743-988051d54abc' User entered 'No (N)'	System	25 Aug 2020 21:47:31
	System	25 Aug 2020 21:47:31

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-25T17:47:07', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'e113a3e5-0e10-42b6-9743-988051d54abc' User entered 'No (N)'	System	25 Aug 2020 21:47:31
	System	25 Aug 2020 21:47:31

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-25T17:47:27', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'e113a3e5-0e10-42b6-9743-988051d54abc' User entered 'None (1)'	System	25 Aug 2020 21:47:31
	System	25 Aug 2020 21:47:31

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:58:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-25T17:47:29', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'e113a3e5-0e10-42b6-9743-988051d54abc' User entered '25 Aug 2020 17:47'	System	25 Aug 2020 21:47:31
	System	25 Aug 2020 21:47:31

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 6'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-26T17:38:50', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '7b5a821b-7dfe-463f-b811-6a3e1762f500'	System	26 Aug 2020 21:39:12
User entered 'None (1)'	System	26 Aug 2020 21:39:12

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:58:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-26T17:38:53', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '7b5a821b-7dfe-463f-b811-6a3e1762f500'	System	26 Aug 2020 21:39:12
User entered 'No (N)'	System	26 Aug 2020 21:39:12

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-26T17:38:56', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '7b5a821b-7dfe-463f-b811-6a3e1762f500'	System	26 Aug 2020 21:39:12
User entered 'No (N)'	System	26 Aug 2020 21:39:12

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-26T17:39:07', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '7b5a821b-7dfe-463f-b811-6a3e1762f500'	System	26 Aug 2020 21:39:12
User entered 'None (1)'	System	26 Aug 2020 21:39:12

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:58:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-26T17:39:10', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '7b5a821b-7dfe-463f-b811-6a3e1762f500' User entered '26 Aug 2020 17:39'	System	26 Aug 2020 21:39:12
	System	26 Aug 2020 21:39:12

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 7'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-27T17:43:36', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '515fdeef-62cf-4519-9f37-22a0e1659ce2'	System	27 Aug 2020 21:43:49
User entered 'None (1)'	System	27 Aug 2020 21:43:49

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:58:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-27T17:43:38', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '515fdeef-62cf-4519-9f37-22a0e1659ce2'	System	27 Aug 2020 21:43:49
User entered 'No (N)'	System	27 Aug 2020 21:43:49

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-27T17:43:43', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '515fdeef-62cf-4519-9f37-22a0e1659ce2'	System	27 Aug 2020 21:43:49
User entered 'No (N)'	System	27 Aug 2020 21:43:49

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-27T17:43:45', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '515fdeef-62cf-4519-9f37-22a0e1659ce2'	System	27 Aug 2020 21:43:49
User entered 'None (1)'	System	27 Aug 2020 21:43:49

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:58:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-27T17:43:48', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '515fdeef-62cf-4519-9f37-22a0e1659ce2' User entered '27 Aug 2020 17:43'	System	27 Aug 2020 21:43:49
	System	27 Aug 2020 21:43:49

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T13:08:24', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '7b995d1f-ed57-4b36-9d00-b1142de5f234' User entered 'None (0)'	System	21 Aug 2020 17:08:53
	System	21 Aug 2020 17:08:53

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T13:08:27', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '7b995d1f-ed57-4b36-9d00-b1142de5f234' User entered 'None (0)'	System	21 Aug 2020 17:08:53
	System	21 Aug 2020 17:08:53

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T13:08:30', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '7b995d1f-ed57-4b36-9d00-b1142de5f234' User entered 'None (0)'	System	21 Aug 2020 17:08:53
	System	21 Aug 2020 17:08:53

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T13:08:32', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '7b995d1f-ed57-4b36-9d00-b1142de5f234' User entered 'None (0)'	System	21 Aug 2020 17:08:53
	System	21 Aug 2020 17:08:53

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T13:08:34', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '7b995d1f-ed57-4b36-9d00-b1142de5f234' User entered 'None (0)'	System	21 Aug 2020 17:08:53
	System	21 Aug 2020 17:08:53

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T13:08:38', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '7b995d1f-ed57-4b36-9d00-b1142de5f234' User entered 'None (0)'	System	21 Aug 2020 17:08:53
	System	21 Aug 2020 17:08:53

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T13:08:46', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '7b995d1f-ed57-4b36-9d00-b1142de5f234' User entered 'No (N)'	System	21 Aug 2020 17:08:53
	System	21 Aug 2020 17:08:53

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T13:08:49', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '7b995d1f-ed57-4b36-9d00-b1142de5f234' User entered '21 Aug 2020 13:08'	System	21 Aug 2020 17:08:53
	System	21 Aug 2020 17:08:53

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '21 Aug 2020 12:51'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '21 Aug 2020 15:21'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T17:57:01', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '2dc7ddbd-d36c-4b18-99e9-5077fba6c6eb' User entered 'None (0)'	System	21 Aug 2020 21:57:48
	System	21 Aug 2020 21:57:48

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T17:57:11', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '2dc7ddbd-d36c-4b18-99e9-5077fba6c6eb'	System	21 Aug 2020 21:57:48
User entered 'No interference with activity (1)'	System	21 Aug 2020 21:57:48

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T17:57:14', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '2dc7ddbd-d36c-4b18-99e9-5077fba6c6eb' User entered 'None (0)'	System	21 Aug 2020 21:57:48
	System	21 Aug 2020 21:57:48

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T17:57:21', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '2dc7ddbd-d36c-4b18-99e9-5077fba6c6eb' User entered 'None (0)'	System	21 Aug 2020 21:57:48
	System	21 Aug 2020 21:57:48

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T17:57:30', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '2dc7ddbd-d36c-4b18-99e9-5077fba6c6eb' User entered 'None (0)'	System	21 Aug 2020 21:57:48
	System	21 Aug 2020 21:57:48

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T17:57:33', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '2dc7ddbd-d36c-4b18-99e9-5077fba6c6eb' User entered 'None (0)'	System	21 Aug 2020 21:57:48
	System	21 Aug 2020 21:57:48

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T17:57:41', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '2dc7ddbd-d36c-4b18-99e9-5077fba6c6eb' User entered 'No (N)'	System	21 Aug 2020 21:57:48
	System	21 Aug 2020 21:57:48

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-21T17:57:43', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '2dc7ddbd-d36c-4b18-99e9-5077fba6c6eb' User entered '21 Aug 2020 17:57'	System	21 Aug 2020 21:57:48
	System	21 Aug 2020 21:57:48

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '21 Aug 2020 16:16'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 2'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:58:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-22T17:43:18', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '1ef1671e-f8cd-4281-88a4-087ec690f4a8' User entered 'None (0)'	System	22 Aug 2020 21:43:56
	System	22 Aug 2020 21:43:56

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:58:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-22T17:43:28', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '1ef1671e-f8cd-4281-88a4-087ec690f4a8'	System	22 Aug 2020 21:43:56
User entered 'No interference with activity (1)'	System	22 Aug 2020 21:43:56

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:58:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-22T17:43:35', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '1ef1671e-f8cd-4281-88a4-087ec690f4a8' User entered 'None (0)'	System	22 Aug 2020 21:43:56
	System	22 Aug 2020 21:43:56

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:58:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-22T17:43:39', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '1ef1671e-f8cd-4281-88a4-087ec690f4a8' User entered 'None (0)'	System	22 Aug 2020 21:43:56
	System	22 Aug 2020 21:43:56

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:58:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-22T17:43:47', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '1ef1671e-f8cd-4281-88a4-087ec690f4a8' User entered 'None (0)'	System	22 Aug 2020 21:43:56
	System	22 Aug 2020 21:43:56

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:58:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-22T17:43:49', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '1ef1671e-f8cd-4281-88a4-087ec690f4a8' User entered 'None (0)'	System	22 Aug 2020 21:43:56
	System	22 Aug 2020 21:43:56

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-22T17:43:52', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '1ef1671e-f8cd-4281-88a4-087ec690f4a8'	System	22 Aug 2020 21:43:56
User entered 'No (N)'	System	22 Aug 2020 21:43:56

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:58:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-22T17:43:54', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '1ef1671e-f8cd-4281-88a4-087ec690f4a8' User entered '22 Aug 2020 17:43'	System	22 Aug 2020 21:43:56
	System	22 Aug 2020 21:43:56

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 3'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:58:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-23T17:42:26', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'c59fb4f1-c94b-40e7-a06e-3a5cdd5b479d' User entered 'None (0)'	System	23 Aug 2020 21:43:00
	System	23 Aug 2020 21:43:00

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:58:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-23T17:42:32', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'c59fb4f1-c94b-40e7-a06e-3a5cdd5b479d'	System	23 Aug 2020 21:43:00
User entered 'No interference with activity (1)'	System	23 Aug 2020 21:43:00

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:58:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-23T17:42:38', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'c59fb4f1-c94b-40e7-a06e-3a5cdd5b479d' User entered 'None (0)'	System	23 Aug 2020 21:43:00
	System	23 Aug 2020 21:43:00

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:58:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-23T17:42:45', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'c59fb4f1-c94b-40e7-a06e-3a5cdd5b479d' User entered 'None (0)'	System	23 Aug 2020 21:43:00
	System	23 Aug 2020 21:43:00

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:58:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-23T17:42:48', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'c59fb4f1-c94b-40e7-a06e-3a5cdd5b479d' User entered 'None (0)'	System	23 Aug 2020 21:43:00
	System	23 Aug 2020 21:43:00

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:58:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-23T17:42:50', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'c59fb4f1-c94b-40e7-a06e-3a5cdd5b479d' User entered 'None (0)'	System	23 Aug 2020 21:43:00
	System	23 Aug 2020 21:43:00

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-23T17:42:55', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'c59fb4f1-c94b-40e7-a06e-3a5cdd5b479d' User entered 'No (N)'	System	23 Aug 2020 21:43:00
	System	23 Aug 2020 21:43:00

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:58:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-23T17:42:58', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'c59fb4f1-c94b-40e7-a06e-3a5cdd5b479d' User entered '23 Aug 2020 17:42'	System	23 Aug 2020 21:43:00
	System	23 Aug 2020 21:43:00

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 4'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:58:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-24T17:44:20', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '840e3e84-5380-4876-89f3-88cc80234521' User entered 'None (0)'	System	24 Aug 2020 21:44:53
	System	24 Aug 2020 21:44:53

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:58:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-24T17:44:28', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '840e3e84-5380-4876-89f3-88cc80234521'	System	24 Aug 2020 21:44:53
User entered 'No interference with activity (1)'	System	24 Aug 2020 21:44:53

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:58:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-24T17:44:33', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '840e3e84-5380-4876-89f3-88cc80234521' User entered 'None (0)'	System	24 Aug 2020 21:44:53
	System	24 Aug 2020 21:44:53

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:58:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-24T17:44:36', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '840e3e84-5380-4876-89f3-88cc80234521' User entered 'None (0)'	System	24 Aug 2020 21:44:53
	System	24 Aug 2020 21:44:53

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:58:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-24T17:44:42', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '840e3e84-5380-4876-89f3-88cc80234521' User entered 'None (0)'	System	24 Aug 2020 21:44:53
	System	24 Aug 2020 21:44:53

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:58:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-24T17:44:44', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '840e3e84-5380-4876-89f3-88cc80234521' User entered 'None (0)'	System	24 Aug 2020 21:44:53
	System	24 Aug 2020 21:44:53

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-24T17:44:48', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '840e3e84-5380-4876-89f3-88cc80234521' User entered 'No (N)'	System	24 Aug 2020 21:44:53
	System	24 Aug 2020 21:44:53

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:58:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-24T17:44:52', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '840e3e84-5380-4876-89f3-88cc80234521' User entered '24 Aug 2020 17:44'	System	24 Aug 2020 21:44:53
	System	24 Aug 2020 21:44:53

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 5'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:58:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-25T17:47:33', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'b3cbe2f2-1feb-4dce-bfb5-2767b75c39f2'	System	25 Aug 2020 21:47:50
User entered 'None (0)'	System	25 Aug 2020 21:47:50

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:58:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-25T17:47:35', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'b3cbe2f2-1feb-4dce-bfb5-2767b75c39f2' User entered 'None (0)'	System	25 Aug 2020 21:47:50
	System	25 Aug 2020 21:47:50

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:58:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-25T17:47:38', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'b3cbe2f2-1feb-4dce-bfb5-2767b75c39f2'	System	25 Aug 2020 21:47:50
User entered 'None (0)'	System	25 Aug 2020 21:47:50

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:58:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-25T17:47:40', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'b3cbe2f2-1feb-4dce-bfb5-2767b75c39f2' User entered 'None (0)'	System	25 Aug 2020 21:47:50
	System	25 Aug 2020 21:47:50

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:58:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-25T17:47:42', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'b3cbe2f2-1feb-4dce-bfb5-2767b75c39f2' User entered 'None (0)'	System	25 Aug 2020 21:47:50
	System	25 Aug 2020 21:47:50

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:58:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-25T17:47:44', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'b3cbe2f2-1feb-4dce-bfb5-2767b75c39f2' User entered 'None (0)'	System	25 Aug 2020 21:47:50
	System	25 Aug 2020 21:47:50

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-25T17:47:46', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'b3cbe2f2-1feb-4dce-bfb5-2767b75c39f2'	System	25 Aug 2020 21:47:50
User entered 'No (N)'	System	25 Aug 2020 21:47:50

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:58:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-25T17:47:48', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'b3cbe2f2-1feb-4dce-bfb5-2767b75c39f2' User entered '25 Aug 2020 17:47'	System	25 Aug 2020 21:47:50
	System	25 Aug 2020 21:47:50

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 6'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:58:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-26T17:39:24', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'cdade6cf-6a49-4ff0-a87b-d9244d3a96fb' User entered 'None (0)'	System	26 Aug 2020 21:39:49
	System	26 Aug 2020 21:39:49

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:58:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-26T17:39:31', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'cdade6cf-6a49-4ff0-a87b-d9244d3a96fb' User entered 'None (0)'	System	26 Aug 2020 21:39:49
	System	26 Aug 2020 21:39:49

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:58:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-26T17:39:33', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'cdade6cf-6a49-4ff0-a87b-d9244d3a96fb' User entered 'None (0)'	System	26 Aug 2020 21:39:49
	System	26 Aug 2020 21:39:49

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:58:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-26T17:39:36', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'cdade6cf-6a49-4ff0-a87b-d9244d3a96fb' User entered 'None (0)'	System	26 Aug 2020 21:39:49
	System	26 Aug 2020 21:39:49

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:58:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-26T17:39:38', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'cdade6cf-6a49-4ff0-a87b-d9244d3a96fb' User entered 'None (0)'	System	26 Aug 2020 21:39:49
	System	26 Aug 2020 21:39:49

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:58:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-26T17:39:40', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'cdade6cf-6a49-4ff0-a87b-d9244d3a96fb' User entered 'None (0)'	System	26 Aug 2020 21:39:49
	System	26 Aug 2020 21:39:49

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-26T17:39:43', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'cdade6cf-6a49-4ff0-a87b-d9244d3a96fb' User entered 'No (N)'	System	26 Aug 2020 21:39:49
	System	26 Aug 2020 21:39:49

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:58:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-26T17:39:46', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'cdade6cf-6a49-4ff0-a87b-d9244d3a96fb' User entered '26 Aug 2020 17:39'	System	26 Aug 2020 21:39:49
	System	26 Aug 2020 21:39:49

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 7'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:58:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-27T17:43:52', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '24f885b7-9348-4fc8-bdf1-f0e278bc95f4' User entered 'None (0)'	System	27 Aug 2020 21:44:15
	System	27 Aug 2020 21:44:15

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:58:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-27T17:43:57', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '24f885b7-9348-4fc8-bdf1-f0e278bc95f4' User entered 'None (0)'	System	27 Aug 2020 21:44:15
	System	27 Aug 2020 21:44:15

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:58:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-27T17:44:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '24f885b7-9348-4fc8-bdf1-f0e278bc95f4' User entered 'None (0)'	System	27 Aug 2020 21:44:15
	System	27 Aug 2020 21:44:15

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:58:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-27T17:44:02', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '24f885b7-9348-4fc8-bdf1-f0e278bc95f4' User entered 'None (0)'	System	27 Aug 2020 21:44:15
	System	27 Aug 2020 21:44:15

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:58:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-27T17:44:05', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '24f885b7-9348-4fc8-bdf1-f0e278bc95f4' User entered 'None (0)'	System	27 Aug 2020 21:44:15
	System	27 Aug 2020 21:44:15

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:58:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-27T17:44:07', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '24f885b7-9348-4fc8-bdf1-f0e278bc95f4' User entered 'None (0)'	System	27 Aug 2020 21:44:15
	System	27 Aug 2020 21:44:15

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:58:30

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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-27T17:44:10', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '24f885b7-9348-4fc8-bdf1-f0e278bc95f4' User entered 'No (N)'	System	27 Aug 2020 21:44:15
	System	27 Aug 2020 21:44:15

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:58:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-08-27T17:44:12', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '24f885b7-9348-4fc8-bdf1-f0e278bc95f4' User entered '27 Aug 2020 17:44'	System	27 Aug 2020 21:44:15
	System	27 Aug 2020 21:44:15

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:58:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 16:34:51

US3672251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:58:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:28:10

US3672251

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 10:15:24
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'PD NOTED' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 18:58:42
User entered '1 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 18:28:29
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	04 Sep 2020 18:28:10
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 18:28:10

US3672251

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:28:10

US3672251

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 18:28:10

US3672251

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:28:33

US3672251

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '1'	System	04 Sep 2020 18:28:33

US3672251

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:28:44

US3672251

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:28:44

US3672251

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:28:44

US3672251

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 18:28:44

US3672251

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:28:48

US3672251

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '1'	System	04 Sep 2020 18:28:48

US3672251

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:34:03

US3672251

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:34:03

US3672251

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 18:34:03

US3672251

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:34:03

US3672251

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:34:08

US3672251

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '1'	System	14 Sep 2020 18:34:08

US3672251

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:03:51

US3672251

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:03:51

US3672251

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:03:51

US3672251

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'VISIT2'	System	23 Sep 2020 15:03:51

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '23 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '10:06'	(b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '23 Sep 2020 10:06'	System	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '98.0' F	(b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Oral (Oral)'	(b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '81'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'bpm'	System	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '15'	(b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'breaths/min'	System	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '142'	(b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'mmHg'	System	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '95'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'mmHg'	System	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered empty.	System	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered empty.	System	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered empty.	System	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered empty.	System	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered empty.	System	23 Sep 2020 15:04:40

US3672251

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:04:46

US3672251

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:04:46

US3672251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:05:39

US3672251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User closed query 'Per CDM: V2 D29 Study treatment was not given; however, AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify".' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 07:46:13
Query 'Per CDM: V2 D29 Study treatment was not given; however, AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify".' answered with 'ae added.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 20:57:31
User opened query 'Per CDM: V2 D29 Study treatment was not given; however, AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify".' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:40:41
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	(b) (4), (b) (6)	23 Sep 2020 15:05:39

US3672251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

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)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User closed query 'Per CDM: Please complete the Dosing Discontinuation page. Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 07:39:29
Query 'Per CDM: Please complete the Dosing Discontinuation page. Thank you. ' answered with 'completed' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:44:39
User opened query 'Per CDM: Please complete the Dosing Discontinuation page. Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 05:23:04
User entered 'due to injection site reaction on D8, subject declined second vaccination'	(b) (4), (b) (6)	23 Sep 2020 15:05:39

US3672251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered empty.	System	23 Sep 2020 15:05:39

US3672251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:05:39

US3672251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:05:39

US3672251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered empty.	System	23 Sep 2020 15:05:39

US3672251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:05:39

US3672251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered empty.	System	23 Sep 2020 15:05:39

US3672251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered empty.	System	23 Sep 2020 15:05:39

US3672251

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:07:38

US3672251

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:07:38

US3672251

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '10:26'	(b) (4), (b) (6)	23 Sep 2020 15:07:38

US3672251

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '23 Sep 2020 10:26'	System	23 Sep 2020 15:07:38

US3672251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:08:18

US3672251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:58:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	23 Sep 2020 15:08:18

US3672251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:58:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:08:18

US3672251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:58:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '10:17'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:08:18

US3672251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '23 Sep 2020 10:17'	System	23 Sep 2020 15:08:18

US3672251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:58:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	23 Sep 2020 15:08:18

US3672251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:58:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:08:18

US3672251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:58:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:08:18

US3672251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered empty.	System	23 Sep 2020 15:08:18

US3672251

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:08:23

US3672251

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '1'	System	23 Sep 2020 15:08:23

US3672251

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:19:41

US3672251

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '3 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:19:41

US3672251

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:19:41

US3672251

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:19:41

US3672251

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:19:44

US3672251

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '1'	System	06 Oct 2020 15:19:44

US3672251

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 19:53:01

US3672251

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '11 Oct 2020'	(b) (4), (b) (6)	11 Oct 2020 19:53:01

US3672251

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Oct 2020 19:53:01

US3672251

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:53:01

US3672251

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 19:53:07

US3672251

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '1'	System	11 Oct 2020 19:53:07

US3672251

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 19:35:46

US3672251

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:35:46

US3672251

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Oct 2020 19:35:46

US3672251

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 19:35:46

US3672251

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 19:35:51

US3672251

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '1'	System	19 Oct 2020 19:35:51

US3672251

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 20:08:41

US3672251

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:08:41

US3672251

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:08:41

US3672251

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'VISIT3'	System	23 Oct 2020 20:08:41

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:09:30

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:09:30

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '13:05'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:09:30

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '23 Oct 2020 13:05'	System	23 Oct 2020 20:09:30

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '98.0' F	(b) (4), (b) (6)	23 Oct 2020 20:09:30

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:09:30

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:09:30

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '74'	(b) (4), (b) (6)	23 Oct 2020 20:09:30

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'bpm'	System	23 Oct 2020 20:09:30

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '16'	(b) (4), (b) (6)	23 Oct 2020 20:09:30

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'breaths/min'	System	23 Oct 2020 20:09:30

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '132'	(b) (4), (b) (6)	23 Oct 2020 20:09:30

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'mmHg'	System	23 Oct 2020 20:09:30

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '84'	(b) (4), (b) (6)	23 Oct 2020 20:09:30

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered 'mmHg'	System	23 Oct 2020 20:09:30

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50

US3672251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50

US3672251

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:09:36

US3672251

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:09:36

US3672251

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
Query 'Per Vendor Reconciliation: On GCL vendor database, the sample for the immunogenicity assessment performed on 23Oct2020 is reported; however, on clinical database is missing. Please report missing data or clarify thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 11:54:07
User opened query 'Per Vendor Reconciliation: On GCL vendor database, the sample for the immunogenicity assessment performed on 23Oct2020 is reported; however, on clinical database is missing. Please report missing data or clarify thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 22:18:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 20:10:32

US3672251

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:10:32

US3672251

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered '13:05'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:10:32

US3672251

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '23 Oct 2020 13:05'	System	23 Oct 2020 20:10:32

US3672251

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 20:12:24

US3672251

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '1'	System	23 Oct 2020 20:12:24

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 64'	System	21 Aug 2020 16:34:51

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-10-21T04:27:38', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '6c2e0ed2-3029-41ad-9ab0-ced5069fbc95' User entered 'No (N)'	System	21 Oct 2020 08:27:55
	System	21 Oct 2020 08:27:55

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

Have you been exposed to someone with 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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-10-21T04:27:47', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '6c2e0ed2-3029-41ad-9ab0-ced5069fbc95'	System	21 Oct 2020 08:27:55
User entered 'No (N)'	System	21 Oct 2020 08:27:55

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-10-21T04:27:52', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '6c2e0ed2-3029-41ad-9ab0-ced5069fbc95' User entered '21 Oct 2020 04:27:52'	System	21 Oct 2020 08:27:55
	System	21 Oct 2020 08:27:55

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 16:34:51

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 71'	System	21 Aug 2020 16:34:51

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-10-28T04:08:12', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '703e855c-ff21-4bb1-a046-d645af97e013' User entered 'No (N)'	System	28 Oct 2020 08:08:33
	System	28 Oct 2020 08:08:33

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

Have you been exposed to someone with 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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-10-28T04:08:20', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '703e855c-ff21-4bb1-a046-d645af97e013'	System	28 Oct 2020 08:08:33
User entered 'No (N)'	System	28 Oct 2020 08:08:33

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-10-28T04:08:29', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '703e855c-ff21-4bb1-a046-d645af97e013' User entered '28 Oct 2020 04:08:29'	System	28 Oct 2020 08:08:33
	System	28 Oct 2020 08:08:33

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 16:34:51

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 78'	System	21 Aug 2020 16:34:51

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-11-06T12:25:44', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '08ed0387-0f4f-4a54-832b-fe56ed693151'	System	06 Nov 2020 17:26:01
User entered 'No (N)'	System	06 Nov 2020 17:26:01

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

Have you been exposed to someone with 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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-11-06T12:25:52', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '08ed0387-0f4f-4a54-832b-fe56ed693151'	System	06 Nov 2020 17:26:01
User entered 'No (N)'	System	06 Nov 2020 17:26:01

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-11-06T12:25:56', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '08ed0387-0f4f-4a54-832b-fe56ed693151' User entered '06 Nov 2020 12:25:56'	System	06 Nov 2020 17:26:01
	System	06 Nov 2020 17:26:01

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 16:34:51

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered 'Day 92'	System	21 Aug 2020 16:34:51

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-11-19T10:55:50', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'ba789b07-542c-49ed-afe3-1ee4d72cad1c' User entered 'No (N)'	System	19 Nov 2020 15:56:04
	System	19 Nov 2020 15:56:04

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

Have you been exposed to someone with 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 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-11-19T10:55:54', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'ba789b07-542c-49ed-afe3-1ee4d72cad1c'	System	19 Nov 2020 15:56:04
User entered 'No (N)'	System	19 Nov 2020 15:56:04

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-11-19T10:55:59', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'ba789b07-542c-49ed-afe3-1ee4d72cad1c' User entered '19 Nov 2020 10:55:59'	System	19 Nov 2020 15:56:04
	System	19 Nov 2020 15:56:04

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 16:34:51

US3672251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:32:50
Data entry locked.	System	21 Aug 2020 16:34:51
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 16:34:51

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-11-23T04:14:42', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '8e717ac0-d4ff-4982-afae-a499aff44ce3'	System	23 Nov 2020 09:14:54
User entered 'No (N)'	System	23 Nov 2020 09:14:54

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-11-23T04:14:47', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '8e717ac0-d4ff-4982-afae-a499aff44ce3'	System	23 Nov 2020 09:14:54
User entered 'No (N)'	System	23 Nov 2020 09:14:54

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-11-23T04:14:51', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '8e717ac0-d4ff-4982-afae-a499aff44ce3' User entered '23 Nov 2020 04:14:51'	System	23 Nov 2020 09:14:54
	System	23 Nov 2020 09:14:54

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-11-29T05:40:38', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '533e3bb8-fa7f-44ea-869a-6f2c0b770af0' User entered 'No (N)'	System	29 Nov 2020 10:40:53

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-11-29T05:40:46', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '533e3bb8-fa7f-44ea-869a-6f2c0b770af0' User entered 'No (N)'	System	29 Nov 2020 10:40:53

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-11-29T05:40:50', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '533e3bb8-fa7f-44ea-869a-6f2c0b770af0' User entered '29 Nov 2020 05:40:50'	System	29 Nov 2020 10:40:53
	System	29 Nov 2020 10:40:53

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-12-06T06:46:38', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '3e89f10c-492e-495c-9d66-0567917068eb' User entered 'No (N)'	System	06 Dec 2020 11:46:57
	System	06 Dec 2020 11:46:57

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-12-06T06:46:49', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '3e89f10c-492e-495c-9d66-0567917068eb' User entered 'No (N)'	System	06 Dec 2020 11:46:57

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-12-06T06:46:54', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '3e89f10c-492e-495c-9d66-0567917068eb' User entered '06 Dec 2020 06:46:54'	System	06 Dec 2020 11:46:57
	System	06 Dec 2020 11:46:57

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-12-13T05:49:39', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'a4c48b91-5cfa-4567-8d9f-512a0d763f76'	System	13 Dec 2020 10:49:58
User entered 'No (N)'	System	13 Dec 2020 10:49:58

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-12-13T05:49:51', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'a4c48b91-5cfa-4567-8d9f-512a0d763f76'	System	13 Dec 2020 10:49:58
User entered 'No (N)'	System	13 Dec 2020 10:49:58

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-12-13T05:49:55', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'a4c48b91-5cfa-4567-8d9f-512a0d763f76' User entered '13 Dec 2020 05:49:55'	System	13 Dec 2020 10:49:58
	System	13 Dec 2020 10:49:58

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-12-20T07:00:26', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '17b82ba0-2a28-4332-9a66-759db85e5ec3'	System	20 Dec 2020 12:00:43
User entered 'No (N)'	System	20 Dec 2020 12:00:43

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-12-20T07:00:30', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '17b82ba0-2a28-4332-9a66-759db85e5ec3'	System	20 Dec 2020 12:00:43
User entered 'No (N)'	System	20 Dec 2020 12:00:43

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-12-20T07:00:39', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '17b82ba0-2a28-4332-9a66-759db85e5ec3' User entered '20 Dec 2020 07:00:39'	System	20 Dec 2020 12:00:43
	System	20 Dec 2020 12:00:43

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-12-27T06:42:08', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '8787fdcb-b99b-480d-bebb-45821beaaba5' User entered 'No (N)'	System	27 Dec 2020 11:42:18
	System	27 Dec 2020 11:42:18

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-12-27T06:42:12', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '8787fdcb-b99b-480d-bebb-45821beaaba5' User entered 'No (N)'	System	27 Dec 2020 11:42:18

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2020-12-27T06:42:16', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '8787fdcb-b99b-480d-bebb-45821beaaba5' User entered '27 Dec 2020 06:42:16'	System	27 Dec 2020 11:42:18
	System	27 Dec 2020 11:42:18

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-01-03T01:29:10', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'cdc2ab-5f40-470c-bb27-ada8a032d8ad'	System	03 Jan 2021 06:29:45
User entered 'No (N)'	System	03 Jan 2021 06:29:45

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-01-03T01:29:20', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'cdc2ab-5f40-470c-bb27-ada8a032d8ad'	System	03 Jan 2021 06:29:45
User entered 'Yes (Y)'	System	03 Jan 2021 06:29:45

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-01-03T01:29:32', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'cdc2ab-5f40-470c-bb27-ada8a032d8ad'	System	03 Jan 2021 06:29:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Jan 2021 06:29:45

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-01-03T01:29:37', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'cdc2ab-5f40-470c-bb27-ada8a032d8ad' User entered '03 Jan 2021 01:29:37'	System	03 Jan 2021 06:29:45
	System	03 Jan 2021 06:29:45

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-01-10T06:03:11', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '366a5cdd-3215-4747-8f96-ab643b98faba' User entered 'No (N)'	System	10 Jan 2021 11:03:34

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-01-10T06:03:24', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '366a5cdd-3215-4747-8f96-ab643b98faba'	System	10 Jan 2021 11:03:34
User entered 'No (N)'	System	10 Jan 2021 11:03:34

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-01-10T06:03:30', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '366a5cdd-3215-4747-8f96-ab643b98faba' User entered '10 Jan 2021 06:03:30'	System	10 Jan 2021 11:03:34
	System	10 Jan 2021 11:03:34

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-01-17T05:57:52', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '41bf5fd4-a067-4fec-a629-4d4fe4b080d1'	System	17 Jan 2021 10:58:24
User entered 'No (N)'	System	17 Jan 2021 10:58:24

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-01-17T05:58:09', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '41bf5fd4-a067-4fec-a629-4d4fe4b080d1'	System	17 Jan 2021 10:58:24
User entered 'No (N)'	System	17 Jan 2021 10:58:24

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-01-17T05:58:21', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '41bf5fd4-a067-4fec-a629-4d4fe4b080d1' User entered '17 Jan 2021 05:58:21'	System	17 Jan 2021 10:58:24
	System	17 Jan 2021 10:58:24

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-01-24T05:19:21', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'a1cbfc86-8721-45e1-8875-78574c3cb828' User entered 'No (N)'	System	24 Jan 2021 10:19:40

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-01-24T05:19:29', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'a1cbfc86-8721-45e1-8875-78574c3cb828'	System	24 Jan 2021 10:19:40
User entered 'No (N)'	System	24 Jan 2021 10:19:40

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-01-24T05:19:38', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'a1cbfc86-8721-45e1-8875-78574c3cb828' User entered '24 Jan 2021 05:19:38'	System	24 Jan 2021 10:19:40
	System	24 Jan 2021 10:19:40

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-01-31T05:40:38', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'b824554b-29e8-45ae-8d70-42738c0e5747'	System	31 Jan 2021 10:40:50
User entered 'No (N)'	System	31 Jan 2021 10:40:50

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-01-31T05:40:42', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'b824554b-29e8-45ae-8d70-42738c0e5747'	System	31 Jan 2021 10:40:50
User entered 'No (N)'	System	31 Jan 2021 10:40:50

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-01-31T05:40:47', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'b824554b-29e8-45ae-8d70-42738c0e5747' User entered '31 Jan 2021 05:40:47'	System	31 Jan 2021 10:40:50
	System	31 Jan 2021 10:40:50

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-02-07T06:58:48', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '6ee9f260-550c-4b60-995d-6d661cc10130' User entered 'No (N)'	System	07 Feb 2021 11:59:01

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-02-07T06:58:54', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '6ee9f260-550c-4b60-995d-6d661cc10130'	System	07 Feb 2021 11:59:01
User entered 'No (N)'	System	07 Feb 2021 11:59:01

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-02-07T06:58:58', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '6ee9f260-550c-4b60-995d-6d661cc10130'	System	07 Feb 2021 11:59:01
User entered '07 Feb 2021 06:58:58'	System	07 Feb 2021 11:59:01

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-02-14T06:39:52', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '194427e2-f948-4a1d-8291-fcc9e68d206b' User entered 'No (N)'	System	14 Feb 2021 11:40:05

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-02-14T06:39:58', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '194427e2-f948-4a1d-8291-fcc9e68d206b' User entered 'No (N)'	System	14 Feb 2021 11:40:05

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-02-14T06:40:03', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '194427e2-f948-4a1d-8291-fcc9e68d206b' User entered '14 Feb 2021 06:40:03'	System	14 Feb 2021 11:40:05
	System	14 Feb 2021 11:40:05

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-02-21T06:24:13', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '808d3880-383b-4992-830f-45ab9b0c2e7a' User entered 'No (N)'	System	21 Feb 2021 11:24:27
	System	21 Feb 2021 11:24:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-02-21T06:24:20', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '808d3880-383b-4992-830f-45ab9b0c2e7a'	System	21 Feb 2021 11:24:27
User entered 'No (N)'	System	21 Feb 2021 11:24:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-02-21T06:24:25', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '808d3880-383b-4992-830f-45ab9b0c2e7a' User entered '21 Feb 2021 06:24:25'	System	21 Feb 2021 11:24:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-02-28T07:06:58-05:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '014d6c2b-3dce-4d14-8827-36da151e6eb2' User entered 'No (N)'	System	28 Feb 2021 12:07:08
	System	28 Feb 2021 12:07:08

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-02-28T07:07:02-05:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '014d6c2b-3dce-4d14-8827-36da151e6eb2'	System	28 Feb 2021 12:07:08
User entered 'No (N)'	System	28 Feb 2021 12:07:08

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-02-28T07:07:05-05:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '014d6c2b-3dce-4d14-8827-36da151e6eb2'	System	28 Feb 2021 12:07:08
User entered '28 Feb 2021 12:07:05'	System	28 Feb 2021 12:07:08

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-03-07T06:44:34-05:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '72886a35-0e40-422b-a956-77750f4efa13'	System	07 Mar 2021 11:44:45
User entered 'No (N)'	System	07 Mar 2021 11:44:45

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-03-07T06:44:38-05:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '72886a35-0e40-422b-a956-77750f4efa13'	System	07 Mar 2021 11:44:45
User entered 'No (N)'	System	07 Mar 2021 11:44:45

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-03-07T06:44:41-05:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '72886a35-0e40-422b-a956-77750f4efa13'	System	07 Mar 2021 11:44:45
User entered '07 Mar 2021 06:44:41'	System	07 Mar 2021 11:44:45

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-03-14T07:04:32-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '7c615e84-2317-44e7-93ec-4f1ead1185a1'	System	14 Mar 2021 11:04:52
User entered 'No (N)'	System	14 Mar 2021 11:04:52

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-03-14T07:04:44-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '7c615e84-2317-44e7-93ec-4f1ead1185a1'	System	14 Mar 2021 11:04:52
User entered 'No (N)'	System	14 Mar 2021 11:04:52

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-03-14T07:04:49-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '7c615e84-2317-44e7-93ec-4f1ead1185a1' User entered '14 Mar 2021 07:04:49'	System	14 Mar 2021 11:04:52
	System	14 Mar 2021 11:04:52

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-03-21T12:44:05-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'd2c2a759-c5f8-41e7-8bc0-cf5b53e65456'	System	21 Mar 2021 16:44:17
User entered 'No (N)'	System	21 Mar 2021 16:44:17

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-03-21T12:44:08-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'd2c2a759-c5f8-41e7-8bc0-cf5b53e65456'	System	21 Mar 2021 16:44:17
User entered 'No (N)'	System	21 Mar 2021 16:44:17

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-03-21T12:44:14-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'd2c2a759-c5f8-41e7-8bc0-cf5b53e65456'	System	21 Mar 2021 16:44:17
User entered '21 Mar 2021 12:44:14'	System	21 Mar 2021 16:44:17

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-03-28T06:39:30-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '6e509647-3be5-47f2-861a-956858da038e'	System	28 Mar 2021 10:39:51
User entered 'No (N)'	System	28 Mar 2021 10:39:51

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-03-28T06:39:44-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '6e509647-3be5-47f2-861a-956858da038e'	System	28 Mar 2021 10:39:51
User entered 'No (N)'	System	28 Mar 2021 10:39:51

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-03-28T06:39:48-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '6e509647-3be5-47f2-861a-956858da038e' User entered '28 Mar 2021 06:39:48'	System	28 Mar 2021 10:39:51
	System	28 Mar 2021 10:39:51

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-04-04T06:58:37-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'cc5104f3-56c7-4672-a4b9-d207c38dbca9'	System	04 Apr 2021 10:58:46
User entered 'No (N)'	System	04 Apr 2021 10:58:46

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-04-04T06:58:42-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'cc5104f3-56c7-4672-a4b9-d207c38dbca9'	System	04 Apr 2021 10:58:46
User entered 'No (N)'	System	04 Apr 2021 10:58:46

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-04-04T06:58:45-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: 'cc5104f3-56c7-4672-a4b9-d207c38dbca9'	System	04 Apr 2021 10:58:46
User entered '04 Apr 2021 06:58:45'	System	04 Apr 2021 10:58:46

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-04-11T06:47:06-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '24f6ceca-7bc3-42ff-8e01-515e6a94c700'	System	11 Apr 2021 10:47:16
User entered 'No (N)'	System	11 Apr 2021 10:47:16

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-04-11T06:47:10-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '24f6ceca-7bc3-42ff-8e01-515e6a94c700'	System	11 Apr 2021 10:47:16
User entered 'No (N)'	System	11 Apr 2021 10:47:16

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-04-11T06:47:13-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '24f6ceca-7bc3-42ff-8e01-515e6a94c700'	System	11 Apr 2021 10:47:16
User entered '11 Apr 2021 06:47:13'	System	11 Apr 2021 10:47:16

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-04-18T06:49:48-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '39d3780a-b009-4278-8735-124a7b83d7a8'	System	18 Apr 2021 10:49:59
User entered 'No (N)'	System	18 Apr 2021 10:49:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-04-18T06:49:52-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '39d3780a-b009-4278-8735-124a7b83d7a8'	System	18 Apr 2021 10:49:59
User entered 'No (N)'	System	18 Apr 2021 10:49:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-04-18T06:49:57-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '39d3780a-b009-4278-8735-124a7b83d7a8'	System	18 Apr 2021 10:49:59
User entered '18 Apr 2021 06:49:57'	System	18 Apr 2021 10:49:59

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-04-25T06:32:37-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '2a784a86-2929-4f22-996b-82c7e32cf514'	System	02 May 2021 10:42:09
User entered 'No (N)'	System	02 May 2021 10:42:09

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-04-25T06:32:40-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '2a784a86-2929-4f22-996b-82c7e32cf514'	System	02 May 2021 10:42:09
User entered 'No (N)'	System	02 May 2021 10:42:09

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-04-25T06:32:44-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '2a784a86-2929-4f22-996b-82c7e32cf514'	System	02 May 2021 10:42:09
User entered '25 Apr 2021 06:32:44'	System	02 May 2021 10:42:09

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-05-02T06:42:09-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '68c747ff-8046-4173-9ec8-47fc54c5c050'	System	02 May 2021 10:42:18
User entered 'No (N)'	System	02 May 2021 10:42:18

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-05-02T06:42:12-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '68c747ff-8046-4173-9ec8-47fc54c5c050'	System	02 May 2021 10:42:18
User entered 'No (N)'	System	02 May 2021 10:42:18

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-05-02T06:42:15-04:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '68c747ff-8046-4173-9ec8-47fc54c5c050'	System	02 May 2021 10:42:18
User entered '02 May 2021 06:42:15'	System	02 May 2021 10:42:18

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:40:27

US3672251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:40:27
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:40:27

US3672251

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:58:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:25:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-02-28T07:07:12-05:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '6dd75e15-0da3-48ff-9a84-79ab103e4a35'	System	28 Feb 2021 12:07:20
User entered 'No (N)'	System	28 Feb 2021 12:07:20

US3672251

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:58:30

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:25:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (933678BD-5174-46B0-BC81-B3813EDCA7B4)', Time: '2021-02-28T07:07:16-05:00', User OID: 'PatientReportedOutcome (US3672251)', ODM File OID: '6dd75e15-0da3-48ff-9a84-79ab103e4a35' User entered '28 Feb 2021 12:07:16'	System	28 Feb 2021 12:07:20
	System	28 Feb 2021 12:07:20

US3672251

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 15:57:28

US3672251

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:57:28

US3672251

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:57:28

US3672251

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:57:28

US3672251

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:57:43

US3672251

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:12:50
User entered '1'	System	19 Nov 2020 15:57:43

US3672251

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Dec 2020 15:43:27

US3672251

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '22 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 15:43:45
User entered '20 Dec 2020'	(b) (4), (b) (6)	23 Dec 2020 15:43:27

US3672251

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:43:27

US3672251

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:43:27

US3672251

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:43:33

US3672251

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User entered '1'	System	23 Dec 2020 15:43:33

US3672251

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Jan 2021 21:50:12

US3672251

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '21 Jan 2021'	(b) (4), (b) (6)	21 Jan 2021 21:50:12

US3672251

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Jan 2021 21:50:12

US3672251

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 21:50:12

US3672251

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Jan 2021 21:50:18

US3672251

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User entered '1'	System	21 Jan 2021 21:50:18

US3672251

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 18:52:23

US3672251

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '17 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 18:52:23

US3672251

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Feb 2021 18:52:23

US3672251

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 18:52:23

US3672251

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 18:52:29

US3672251

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:37
User entered '1'	System	17 Feb 2021 18:52:29

US3672251

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:41:54

US3672251

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered '28 Mar 2021'	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:41:54

US3672251

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:41:54

US3672251

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	28 Mar 2021 15:41:54

US3672251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:42:01

US3672251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:42:01

US3672251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:42:01

US3672251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
User entered empty.	System	28 Mar 2021 15:42:01

US3672251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:42:01

US3672251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:42:01

US3672251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:42:01

US3672251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:42:01

US3672251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Mar 2021 15:42:01

US3672251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:42:01

US3672251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Mar 2021 15:42:01

US3672251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:42:01

US3672251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Mar 2021 15:42:01

US3672251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:42:01

US3672251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Mar 2021 15:42:01

US3672251

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:42:05

US3672251

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:42:05

US3672251

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:42:15

US3672251

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered '28 Mar 2021'	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:42:15

US3672251

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered '10:09'	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:42:15

US3672251

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
User entered '28 Mar 2021 10:09'	System	28 Mar 2021 15:42:15

US3672251

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Mar 2021 15:42:18

US3672251

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Mar 2021 15:42:18

US3672251

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	20 Apr 2021 15:33:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 21:38:09

US3672251

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	20 Apr 2021 15:33:31
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 21:38:09

US3672251

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	20 Apr 2021 15:33:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 21:38:09

US3672251

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	20 Apr 2021 15:33:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 21:38:09

US3672251

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	20 Apr 2021 15:33:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 21:38:13

US3672251

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 21:38:13

US3672251

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

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Jan 2021 18:16:54

US3672251

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

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	31 Jan 2021 18:16:54

US3672251

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

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	31 Jan 2021 18:16:54

US3672251

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

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User entered 'UNBLND_DECIDE'	System	31 Jan 2021 18:16:54

US3672251

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

Form: Unblinding

Generated On: 11 Aug 2021 22:58:30

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '31 Jan 2021'	(b) (4), (b) (6)	31 Jan 2021 18:17:11

US3672251

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

Form: Unblinding

Generated On: 11 Aug 2021 22:58:30

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:14:50

US3672251

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

Form: Unblinding

Generated On: 11 Aug 2021 22:58:30

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Jan 2021 18:17:11

US3672251

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

Form: Unblinding

Generated On: 11 Aug 2021 22:58:30

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:34
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:14:50

US3672251

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

Form: Unblinding

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	31 Jan 2021 18:17:11

US3672251

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

Form: Unblinding

Generated On: 11 Aug 2021 22:58:30

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	31 Jan 2021 18:17:11

US3672251

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

Form: Unblinding

Generated On: 11 Aug 2021 22:58:30

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	31 Jan 2021 18:17:11

US3672251

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

Form: Unblinding

Generated On: 11 Aug 2021 22:58:30

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Not Administered (NA)'	(b) (4), (b) (6)	31 Jan 2021 18:17:11

US3672251

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

Form: Unblinding

Generated On: 11 Aug 2021 22:58:30

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Jan 2021 18:17:11

US3672251

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

Form: Unblinding

Generated On: 11 Aug 2021 22:58:30

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User entered empty.	System	31 Jan 2021 18:17:11

US3672251

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

Form: Unblinding

Generated On: 11 Aug 2021 22:58:30

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User entered '1'	System	31 Jan 2021 18:17:11

US3672251

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered empty.	System	31 Jan 2021 19:00:57
DataPoint set to visible.	System	31 Jan 2021 18:17:11

US3672251

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered missing code ND - Not Done.	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered empty.	System	31 Jan 2021 19:00:57
DataPoint set to visible.	System	31 Jan 2021 18:17:11

US3672251

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '31 Jan 2021'	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '11:26'	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered '31 Jan 2021 11:26'	System	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '98.4' F	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '88'	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'bpm'	System	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '14'	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'breaths/min'	System	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '138'	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'mmHg'	System	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '82'	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'mmHg'	System	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered missing code ND - Not Done.	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered empty.	System	31 Jan 2021 19:00:57
DataPoint set to visible.	System	31 Jan 2021 18:17:11

US3672251

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '12:27'	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered '31 Jan 2021 12:27'	System	31 Jan 2021 19:00:57

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '98.6' F	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '83'	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'bpm'	System	31 Jan 2021 19:00:57

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '14'	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'breaths/min'	System	31 Jan 2021 19:00:57

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '128'	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'mmHg'	System	31 Jan 2021 19:00:57

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '84'	(b) (4), (b) (6)	31 Jan 2021 19:00:57

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:40
User entered 'mmHg'	System	31 Jan 2021 19:00:57

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Jan 2021 19:01:06

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:30

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '31 Jan 2021'	(b) (4), (b) (6)	31 Jan 2021 19:01:06

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Jan 2021 19:01:35

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4), (b) (6)	31 Jan 2021 19:01:35

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

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)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4), (b) (6)	31 Jan 2021 19:01:35

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User entered 'mRNA-1273'	System	31 Jan 2021 19:01:35
DataPoint set to visible.	System	31 Jan 2021 18:17:11

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	31 Jan 2021 19:01:35

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '11:56'	(b) (4), (b) (6)	31 Jan 2021 19:01:35

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User entered '31 Jan 2021 11:56'	System	31 Jan 2021 19:01:35

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	31 Jan 2021 19:01:35

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User entered 'ONCE'	System	31 Jan 2021 19:01:35

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:30

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User entered 'INTRAMUSCULAR'	System	31 Jan 2021 19:01:35

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Jan 2021 18:17:34

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '31 Jan 2021'	(b) (4), (b) (6)	31 Jan 2021 18:17:34

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '11:34'	(b) (4), (b) (6)	31 Jan 2021 18:17:34

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User entered '31 Jan 2021 11:34'	System	31 Jan 2021 18:17:34

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:58:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Jan 2021 18:17:51

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:58:30

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	31 Jan 2021 18:17:51

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:58:30

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '11:15'	(b) (4), (b) (6)	31 Jan 2021 18:17:51

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:58:30

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User entered '31 Jan 2021 11:15'	System	31 Jan 2021 18:17:51

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Jan 2021 18:17:57

US3672251

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:49
User entered '1'	System	31 Jan 2021 18:17:57

US3672251

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:41:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Feb 2021 23:32:39

US3672251

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:41:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '7 Feb 2021'	(b) (4) (b) (4), (b) (6)	07 Feb 2021 23:32:39

US3672251

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:41:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Feb 2021 23:32:39

US3672251

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:41:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4), (b) (6)	07 Feb 2021 23:32:39

US3672251

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:41:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Feb 2021 23:32:43

US3672251

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:41:42
User entered '1'	System	07 Feb 2021 23:32:43

US3672251

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:30

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:41:42
User entered '1'	System	07 Feb 2021 23:32:43
DataPoint set to visible.	System	07 Feb 2021 23:32:43

US3672251

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 20:01:16

US3672251

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '28 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:01:16

US3672251

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:01:16

US3672251

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User entered 'OLD29'	System	01 Mar 2021 20:01:16

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:02:01

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:02:01

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:02:01

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User entered empty.	System	01 Mar 2021 20:02:01

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:02:01

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 20:02:01

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 20:02:01

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 20:02:01

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User entered empty.	System	01 Mar 2021 20:02:01

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:02:01

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User entered empty.	System	01 Mar 2021 20:02:01

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:02:01

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User entered empty.	System	01 Mar 2021 20:02:01

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:02:01

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User entered empty.	System	01 Mar 2021 20:02:01

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47

US3672251

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 23:01:47

US3672251

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:02:07

US3672251

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:02:07

US3672251

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User closed query 'Per GCL Lab Recon:LB4 Immuno: There is a visit mismatch between EDC & GCL per latest Preclarus reports for this sample dated 28 FEB 2021, as it is updated under OL-D29 here in EDC, however in PPD GCL it is updated under OL-D57. Please kindly confirm which data is correct and update accordingly in EDC or Preclarus as necessary by sending a DCF. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 08:26:59
Query 'Per GCL Lab Recon:LB4 Immuno: There is a visit mismatch between EDC & GCL per latest Preclarus reports for this sample dated 28 FEB 2021, as it is updated under OL-D29 here in EDC, however in PPD GCL it is updated under OL-D57. Please kindly confirm which data is correct and update accordingly in EDC or Preclarus as necessary by sending a DCF. Thank you. ' answered with 'DCF sent' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 12:11:59
User opened query 'Per GCL Lab Recon:LB4 Immuno: There is a visit mismatch between EDC & GCL per latest Preclarus reports for this sample dated 28 FEB 2021, as it is updated under OL-D29 here in EDC, however in PPD GCL it is updated under OL-D57. Please kindly confirm which data is correct and update accordingly in EDC or Preclarus as necessary by sending a DCF. Thank you. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 14:39:33
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 20:02:37

US3672251

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User closed query 'Per GCL Lab Recon: Immuno: It appears there is a collection date mismatch between EDC & PPD GCL for this sample, as in PPD GCL, it is recorded as collected on "26 FEB 2021", however here in EDC, it is recorded as collected on "28 FEB 2021". Please confirm the correct sample collection date in the response, and then please update the correct date in EDC or Preclarus as necessary by sending a DCF. Thank you. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 14:38:33
Query 'Per GCL Lab Recon: Immuno: It appears there is a collection date mismatch between EDC & PPD GCL for this sample, as in PPD GCL, it is recorded as collected on "26 FEB 2021", however here in EDC, it is recorded as collected on "28 FEB 2021". Please confirm the correct sample collection date in the response, and then please update the correct date in EDC or Preclarus as necessary by sending a DCF. Thank you. ' answered with 'DCF submitted' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 19:52:22
User opened query 'Per GCL Lab Recon: Immuno: It appears there is a collection date mismatch between EDC & PPD GCL for this sample, as in PPD GCL, it is recorded as collected on "26 FEB 2021", however here in EDC, it is recorded as collected on "28 FEB 2021". Please confirm the correct sample collection date in the response, and then please update the correct date in EDC or Preclarus as necessary by sending a DCF. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 08:42:03
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '28 Feb 2021'	(b) (4), (b) (6)	01 Mar 2021 20:02:37

US3672251

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '11:10'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:02:37

US3672251

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:47
User entered '28 Feb 2021 11:10'	System	01 Mar 2021 20:02:37

US3672251

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:58:30

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 20:55:55

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User closed query 'Per DM CLR: Please review AE and please update to specify if this 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) (4), (b) (6)	22 Dec 2020 04:25:37
Query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. 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)	18 Dec 2020 17:10:43
User opened query 'Per DM CLR: Please review AE and please update to specify if this 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)	28 Nov 2020 14:51:33
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site redness - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 20:58:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 20:58:31
Data point term sent to Coder	System	23 Oct 2020 20:57:38
User entered 'redness at injection site'	(b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 06:26:12
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' answered with 'confirm meets reporting requirements' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 17:12:33
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 14:51:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '30 Aug 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4) System	27 Oct 2020 19:46:06
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	27 Oct 2020 19:46:06
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	27 Oct 2020 19:45:02
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '1'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 20:56:56

US3672251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:30

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 20:56:56

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:58:30

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 15:18:02

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 15:19:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 15:19:35
Data point term sent to Coder	System	24 Aug 2020 15:19:03
User entered 'amlodipine'	(b) (4), (b) (6)	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '5'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'un Nov 2019'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 15:18:42

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 15:20:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 15:20:35
Data point term sent to Coder	System	24 Aug 2020 15:20:03
User entered 'Vitamin B12'	(b) (4), (b) (6)	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'vitamin B12 deficiency'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '6000'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'mcg'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 15:19:23

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 15:21:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 15:21:36
Data point term sent to Coder	System	24 Aug 2020 15:21:05
User entered 'Vitamin D'	(b) (4), (b) (6)	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'vitamin D deficiency'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '250'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'mcg'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'un Jan 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 15:20:04

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
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)	11 Oct 2020 19:56:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Oct 2020 19:56:26
Data point term sent to Coder	System	11 Oct 2020 19:54:57
User entered 'Influenza Vaccine'	(b) (4), (b) (6)	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Influenza Prophylaxis'	(b) (4), (b) (6)	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '1'	(b) (4), (b) (6)	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Other (OTHER)'	(b) (4), (b) (6)	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'injection'	(b) (4) (b) (4), (b) (6)	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '10 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '0'	(b) (4), (b) (6)	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '10 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User entered empty.	System	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User entered empty.	System	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:28:35
User entered empty.	System	11 Oct 2020 19:54:08

US3672251

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:58:30

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:17:55

US3672251

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:58:30

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:06
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered '23 Sep 2020'	(b) (4), (b) (6)	27 Oct 2020 19:45:02

US3672251

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:58:30

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:06
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 19:46:06
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	(b) (4), (b) (6)	27 Oct 2020 19:45:02

US3672251

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:58:30

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:06
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:03:51
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)	05 Mar 2021 11:21:59
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 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 18:14:20
User entered 'AE#1' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 18:14:14
Query 'Per CDM: Please record AE record number instead of details. ' canceled (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:14:02
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 14:14:00
User opened query 'Per CDM: Please record AE record number instead of details. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 15:18:44
User entered 'PARTICIPANT DECLINED DUE TO INJECTION SITE REACTION ON D8, SUBJECT DECLINED SECOND VACCINATION' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 19:45:37
User entered 'DUE TO INJECTION SITE REACTION ON D8, SUBJECT DECLINED SECOND VACCINATION'	(b) (4), (b) (6)	27 Oct 2020 19:45:02